Creation Date : 18/01/2018

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen Germany	0044	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses - *MD 1109 - Active devices for patient positioning and transport			
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			without medical devices according to Commission Regulation (EU) No 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, thermic sterilisation with dry heat

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry Dublin 9 Ireland	0050	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1106 - Active dental devices - *MD 1108 - Active rehabilitation devices and active			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43 20138 - MILANO Italy	0051	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		devices	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	exclusion medical devices class III

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC type-examination	Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC type-examination	Annex III	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1109 - Active devices for patient positioning and transport	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Mit International Testing S.r.l. Via G.Leopardi, 14 20123 - Milano (MI) Italy	0068	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0106 - Non-active instruments	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Excluding class III Medical Devices and hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC verification EC declaration of conformity (full quality	Annex IV Annex II Annex V	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC type-examination EC declaration of	Annex III Annex II	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1300 - Monitoring devices	EC declaration of	Annex II	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom	0086	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software			
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
LLOYD'S REGISTER QUALITY ASSURANCE LTD (0088) 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom	0088	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia			
		*MDS 7001 - Medical devices incorporating medicinal			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
SGS United Kingdom Limited Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA United Kingdom	0120	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1108 - Active rehabilitation devices and active prostheses	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance	Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Excluding Breast Implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65 80339 MÜNCHEN Germany	0123	*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software			
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex III	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC type-examination EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion *MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation with liquid sterilants
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DEKRA Certification GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices	conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany	0197	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0204 - Non-active soft tissue implants	system EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system EC type-examination	Annex II Annex III Annex IV	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC verification Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1111 - Software			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			for active medical devices only
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 FRANKFURT AM MAIN Germany	0297	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	system Production quality assurance	Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance	Annex II Annex V	vascular implants only

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS Campezo 1. Edificio 8 28022 MADRID Spain	0318	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation	conformity (production quality assurance) EC declaration of conformity (product quality assurance)		

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		(IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		(IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7005 - Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
DEKRA Certification B.V. Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands	0344	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0403 - Dental implants *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ISTITUTO SUPERIORE DI SANITA' Viale Regina Elena, 299 00161 - ROMA Italy	0373	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable	EC type-examination	Annex III	Annex III limited to ophthalmic

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	solutions
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0110 - Non-active medical devices for ingestion	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	Annex III limited to injectable visco-elastic solutions for intra-articular use
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC type-examination EC declaration of conformity (full quality assurance system)	Annex III Annex II Annex V	Annex III limited intradermal fillers

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0402 - Dental materials	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification	Annex III Annex IV	Limited to accelerator for hadron therapy and related dose delivery system
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam, moist heat sterilisation, radiation sterelisation (gamma, electron beam)

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
RISE Research Institutes of Sweden AB Box 857 501 15 BORAS Sweden	0402	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	Production quality assurance Product quality assurance	Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Bone-anchored implants for dental and cranio-facial reconstruction
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Bone-anchored implants for dental and cranio-facial reconstruction
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1103 - Devices for stimulation or inhibition	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TÜV AUSTRIA SERVICES GMBH Deutschstraße 10 1230 WIEN Austria	0408	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	neurological and neurosurgical implants excluded
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			tissues according directive 2003/32/EC excluded
		*MDS 7003 - Medical devices incorporating derivates of			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
INTERTEK SEMKO AB Torshamnsgatan 43 Box 1103 SE-164 22 KISTA Sweden	0413	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing *MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (product quality assurance)		

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
ICIM S.P.A. Piazza Don Enrico Mapelli, 75 20099 - Sesto San Giovanni (MI) Italy	0425	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices and hyperbaric chambers
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Exclusion of class III medical

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		physiological parameters	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ITALCERT SRL Viale Sarca, 336 20126 - MILANO Italy	0426	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except surgically devices, intended for transient use, in direct contact with central nervous system
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Exclusion of class III medical

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1105 - Active ophthalmologic devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Exclusion of medical devices utilising tissues of animal origin under Commission Regulation

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					(EU) n. 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Laboratoire national de métrologie et d'essais / G-MED 1, rue Gaston Boissier 75724 PARIS Cedex 15 France	0459	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)			
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Chemical sterilization/Dry heat sterilization/Hydrogen peroxid with or without plasma process sterilization/Ultra High Temperature Infusion sterilization process
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
AMTAC CERTIFICATION SERVICES LTD Davy Avenue, Knowlhill Milton Keynes MK5 8NL United Kingdom	0473	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Excluding breast implants
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and	Full quality assurance system	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		instruments	Production quality assurance Product quality assurance	Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Excluding Class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Excluding Class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding Class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7006 - Medical devices in sterile condition			
KIWA CERMET ITALIA S.P.A. Via Cadriano, 23 40057 - Cadriano di Granarolo (BO) Italy	0476	*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices, except hip, knee and shoulder joint replacements.
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices, except surgically devices, intended for transient use, in direct contact with central nervous system

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices and hyperbaric chambers for oxygen therapy
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1108 - Active rehabilitation devices and active prostheses	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III medical devices and devices for magnetic

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		radiation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	resonance
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Excluding class III medical devices
		*MDS 7006 - Medical devices in sterile condition			Excluding class III medical devices, except surgically devices, intended for transient use, in direct contact with central nervous system; hip, knee and shoulder joint replacements
Eurofins Product Testing Italy S.r.l. Via Courgnè, 21 10156 - TORINO (TO) Italy	0477	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable	EC type-examination	Annex III	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0107 - Contraceptive medical devices	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Only class IIa medical devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices and devices for magnetic resonance
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Excluding class III medical devices
		*MDS 7005 - Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)			Excluding class III medical devices
		*MDS 7006 - Medical devices in sterile condition			Excluding class III medical devices
ecm-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH Bismarckstraße 106 52066 Aachen Germany	0481	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system EC type-examination Production quality assurance Product quality assurance	Annex II Annex III Annex V Annex VI	Only stents, implantable catheters, vascular grafts, occlusion systems
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Only introcular lenses
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system EC type-examination Production quality assurance Product quality assurance	Annex II Annex III Annex V Annex VI	Annex III: Only infusion sets, transfusion sets, catheters, tubing systems for extra-corporal circulation
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	only products, which are based on spring tension (pre-loaded) or gas release for pressure build-up, e.g. drug dosers
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	only wound drainage systems and accessories for HF surgery (e.g. scissors, pliers)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Only medical devices in small pressure vessels (e.g. coolant sprays) for localized application and medical devices, where heat or cold is generated by chemical or physical processes (e.g. hot/cold packs) for localized application

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Only devices with existing TSE Certificate of Suitability for the starting materials issued by the European Directorate for the Qualits of Medicines (EDQM)
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH Pilatuspool 2 20355 HAMBURG Germany	0482	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion *MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			for active medical devices only
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0105 - Non-active ophthalmologic devices	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	Production quality assurance Product quality assurance	Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	except hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	except external pacemakers and heart defibrillators
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädter Strasse 20 09232 Hartmannsdorf Germany	0494	*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system	Annex II Annex III	excluding class III devices (valid for the complete scope)

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC type-examination EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system EC type-examination	Annex II Annex III	excluding class III devices (valid for the complete scope)

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	excluding class III devices (valid for

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1401 - Devices utilising ionizing radiation	system EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	the complete scope)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
VTT Expert Services Oy PO Box 345 FI-33101 Tampere Finland	0537	*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1111 - Software	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1400 - Devices for radiation therapy and thermo therapy	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1403 - Devices for hyperthermia / hypothermia	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Excluding class III
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation (gamma, x-ray, electron beam), others (need to be specified)
Presafe Denmark A/S Tuborg Parkvej 8 DK-2900 Hellerup Denmark	0543	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding orthopaedic implants ref. 2005/50/EEC and bone cement

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1301 - Monitoring devices of non-vital physiological parameters	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Only products not included in Directive 2003/32/EC
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
CERTIQUALITY S.R.L. - ISTITUTO DI CERTIFICAZIONE DELLA QUALITA' Via G. Giardino, 4 20123 - MILANO Italy	0546	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding hyperbaric chambers and all devices depending on a source of electrical energy. Exclusion of class III medical devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo	EC declaration of	Annex II	Excluding medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1403 - Devices for hyperthermia / hypothermia	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	depending on a source of electrical energy. Exclusion of class III medical devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SGS FIMKO OY P.O. Box 30 (Särkiniementie 3) 00211 HELSINKI Finland	0598	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only; III, IV: Hyperbaric chambers only
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only; III, IV: Nerve and muscle stimulator only
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only; III, IV: Dental units and dental patient chairs only
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active	EC type-examination EC verification	Annex III Annex IV	II: Up to class IIb only; III, IV: Neurological and muscular

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	rehabilitation devices only
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only; III, IV: X-ray devices only
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only; III, IV: Magnetic resonance imaging (MRI) devices only
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	II: Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MD 1400 - Devices for radiation therapy and thermo	EC type-examination	Annex III	II: Up to class IIb only; III, IV:

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	Surgical ultrasoud devices only
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	II: Up to class IIb only
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			II: Up to class IIb only
		*MDS 7006 - Medical devices in sterile condition			II: Up to class IIb only
Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH Dovestraße 6 10587 Berlin Germany	0633	*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1112 - Medical gas supply systems and parts thereof *MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0106 - Non-active instruments *MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters - *MD 1301 - Monitoring devices of non-vital physiological parameters	quality assurance) EC declaration of conformity (product quality assurance)		
		*MDS 7004 - Medical devices referencing the Directive			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ Kopernikusgasse 24/1 8010 GRAZ Austria	0636	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7007 - Medical devices utilising micromechanics			
NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY Smyrnis 15 165 62 GLYFADA Greece	0653	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0107 - Contraceptive medical devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (product quality assurance)	Annex II Annex VI	Respiratory devices only
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Only for physiotherapy
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Only for physiotherapy
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			Only for MD Codes referred above
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Only for MD Codes referred above
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, dry heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) - Only for MD Codes referred above
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Only for MD Codes referred above
Eurofins Product Service GmbH Storkower Straße 38c 15526 REICHENWALDE Germany	0681	*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MDS 7004 - Medical devices referencing the Directive			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2006/42/EC on machinery			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
THERAPEUTIC GOODS ADMINISTRATION 136 Narrabundah Lane Symonston ACT Australia	0805	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
UL INTERNATIONAL (UK) LTD Wonersh House Building C The Guildway Old Portsmouth Road Guildford GU3 1LR United Kingdom	0843	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to sterile single use devices, class IIb and below
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Limited to sterile single use devices and surgical instruments, class IIb and below

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Class IIb and below
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Class IIb and below
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Class IIb and below

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Class IIb and below
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to sterile single use devices, class IIb and below
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Class IIb and below

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Class IIb and below
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Class IIb and below
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Class IIb and below
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system)	Annex II	Limited to Cardiac catheters
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	No class III or implants

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	No class III or implants
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					specified)
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközmin#sít# és Kórháztechnikai Igazgatóság (National Institute of Pharmacy and Nutrition) Zrínyi u. 3 H-1051 Budapest Hungary	1011	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Annex III. designation excluding materials of desinfecting, cleaning and rinsing . For Annex II., V., VI. there are no limitations.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC type-examination EC declaration of conformity (full quality	Annex III Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation,	EC type-examination EC declaration of	Annex III Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		infusion and haemopheresis	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC type-examination EC declaration of conformity (full quality assurance system)	Annex III Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Excluding breast and body shaping implants
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC declaration of conformity (full quality	Annex III Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Designation excludes products related 2003/32/EC BSE/TSE field. Designation includes Annex 2 and 5.
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					formaldehyde sterilisation, moist heat sterilisation
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p. Pod Lisem 129 171 02 PRAHA 71 - Troja Czech Republic	1014	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. T. Bati 299 Louky, 76302 ZLIN Czech Republic	1023	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb plus epidural sets
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Limited to devices of Classes Im,

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	Is, IIa, IIb plus balloon catheters plus stent delivery systems
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	Limited to devices of Classes Im, Is, IIa, IIb

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to cardiovascular stents including stent inserting tools plus cardiac valves not containing animal tissues
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Limited to devices of the Class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of the Class IIb oesophageal, ureteral and biliary stents
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of the Class IIb plus injection implants based on hyaluronic acid and hyaluronic acid derivates
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Limited to devices of Classes Is, IIa, IIb plus wound dressing being wholly or mainly absorbed and/or incorporating medicinal substances

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Is, IIa, IIb plus devices being wholly or mainly absorbed plus sutures for the central circulatory system
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Is, IIa, IIb plus wound care devices being wholly or mainly absorbed and/or incorporating medicinal substances
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Is, IIa, IIb
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes IIa, IIb
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, IIa, IIb
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
		*MD 1400 - Devices for radiation therapy and thermo	EC declaration of	Annex II	Limited to devices of Classes Im,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1403 - Devices for hyperthermia / hypothermia	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	Is, IIa, IIb
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			Limited to devices sterilised by one of the following: Aseptic filling, Ethylene oxide sterilisation, Radiation sterilisation, Moist heat sterilisation
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			Limited to devices being wholly or mainly absorbed
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Limited to devices of Classes Im, Is, IIa, IIb
Schweizerische Vereinigung für Qualitäts- und Managementsysteme Bernstrasse 103 3052 Zollikofen Switzerland	1250	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		devices	assurance Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Production quality assurance Product quality assurance	Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	excluding heart-lung machine
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	only respiratory devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1108 - Active rehabilitation devices and active prostheses	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
QS Zürich AG Postfach 6335 CH-8050 Zürich Switzerland	1254	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Single-use medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Single-use medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Reusable instruments
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Single-use medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	Single-use medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0107 - Contraceptive medical devices	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Single-use medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1109 - Active devices for patient positioning and transport	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
ENTE CERTIFICAZIONE MACCHINE SRL Via Ca' Bella, 243/A - loc. Castello di Serravalle 40053 Valsamoggia (BO) Italy	1282	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ Trzaska cesta 2 1000 LJUBLJANA Slovenia	1304	*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Annex III and IV lasers only
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Only infant incubators included
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Included only devices for

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	respiratory devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	Annex III and IV lasers only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		devices	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Included only devices for injection, infusion and transfusion

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Excluding formaldehyde sterilisation
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
BUREAU VERITAS ITALIA S.P.A. Via Miramare, 15 20126 - MILANO Italy	1370	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices, hyperbaric chambers for oxygen therapy and medical gas pipeline systems
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Excluding class III medical devices
		*MDS 7006 - Medical devices in sterile condition			Excluding class III medical devices
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. ul. Klobucka 23A 02-699 Warszawa Poland	1434	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SGS Belgium NV Noorderlaan 87 BE-2030 Antwerpen Belgium	1639	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	No class III medical devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to accessories (e.g. lubricants etc) and male/female condoms. No diaphragm's or IUD's
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to devices such as receptacles, petri dishes, pipettes or syringes. No media, substances or mixture of substances.
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices. No joints (partial or complete).

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to implantable holders used in radiotherapy (brachytherapy) and class IIb spinal Implants, spinal stents and cervical cage.
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to clamps and staples.
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0400 - Non-active dental devices and accessories	EC declaration of	Annex II	No class III medical devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0401 - Non-active dental equipment and instruments	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to crowns, prostheses and bridges.
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Only parts (e.g. connectors, flow meters, Venturi, plastic tubing,…). No complete gas supply systems. No medical glasses.
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	No class III medical devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. No devices intended for the monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient.
		*MD 1400 - Devices for radiation therapy and thermo	EC declaration of	Annex II	No class III medical devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1401 - Devices utilising ionizing radiation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			No class III medical devices.
		*MDS 7006 - Medical devices in sterile condition			No class III medical devices. For ETO, irradiation, moist heat, aseptic process and clean rooms technologies
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			No class III medical devices.
TURKISH STANDARDS INSTITUTION (TSE) Necatibey Cad. No. 112, 06100 Bakanliklar Ankara Turkey	1783	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		measuring function			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DARE!! Certifications Vijzelmolenlaan 7 NL-3447 GX Woerden Netherlands	1912	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification	Annex III Annex IV	Limited to devices for infusion. Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	Limited to non sterile class Im, IIa

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters	EC verification	Annex IV	and IIb devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification	Annex III Annex IV	Limited to non sterile class Im, IIa and IIb devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Limited to non sterile class Im, IIa and IIb devices
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Limited to non sterile class Im, IIa and IIb devices
TUV Rheinland Italia SRL Via Mattei, 3 20010 - Pogliano Milanese (MI) Italy	1936	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices and hyperbaric chambers for oxygen therapy
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Kiwa Belgelendirme Hizmetleri A.#. Tepeören Mevkii Ankara Asfalt# Maret Arkas# ITOSB 9. Cadde No: 15 Tuzla Istanbul Turkey	1984	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0107 - Contraceptive medical devices *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1111 - Software			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1108 - Active rehabilitation devices and active prostheses *MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion *MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC,			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Szutest Uygunluk De#erlendirme A.#. Yukar# Dudullu Mahallesi Nato Yolu Caddesi Çam Sokak No: 7 Ümraniye #STANBUL Turkey	2195	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0107 - Contraceptive medical devices	assurance system) EC declaration of conformity (production quality assurance)		
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation			
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
3EC International a.s. 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA Bratislava 82105 Slovakia	2265	*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			excluding Regulation 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TUV NORD Polska Sp. z o.o ul. Mickiewicza 29 40-085 Katowice Poland	2274	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	.
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	without acitive prostheses
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system)	Annex II	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DQS Polska Sp. z o.o ul. Post#pu 17A 02-676 Warszawa Poland	2282	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	excluding dialysers

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.#. Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA Ankara	2292	*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
Turkey		- *MD 0303 - Other medical devices for wound care *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (production quality assurance)		

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft. Gyár u. 2. Budaörs Hungary	2409	*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care	assurance)		

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1111 - Software - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			regarding Annex II, V, VI
		*MDS 7004 - Medical devices referencing the Directive			regarding Annex II, V, VI

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			regarding Annex II, V, VI Including aseptic processing, ethylene oxide gas sterilisation (EOG), radiation sterilization (gamma,x-ray, electron beam), moist heat sterilization
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			regarding Annex II, V, VI
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			regarding Annex II, V, VI
DNV GL Nemko Presafe AS Veritasveien 3 1363 Høvik Norway	2460	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		(IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care			
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others.
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			