Name and address of the notified bodies	ID	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 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 0100 - General non-active, non-implantable medical devices  - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	assurance Product quality assurance	Annex II Annex IV Annex V Annex VI Annex VI Annex VI Annex V Annex V	

### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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 Full quality assurance \*MD 1100 - General active medical devices Annex II system - \*MD 1101 - Devices for extra-corporal circulation, Annex III infusion and haemopheresis EC type-examination Annex IV - \*MD 1102 - Respiratory devices, devices including EC verification Annex V hyperbaric chambers for oxygen therapy, inhalation Production quality Annex VI anaesthesia assurance - \*MD 1103 - Devices for stimulation or inhibition Product quality assurance - \*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

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1111 - Software	EC verification	Annex IV	
			EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1201 - Imaging devices utilising ionizing	system	Annex III	
		radiation	EC type-examination	Annex IV	
		- *MD 1202 - Imaging devices utilising non-ionizing radiation	EC verification Production quality assurance	Annex V Annex VI	
			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)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)		

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1112 - Medical gas supply systems and parts	EC verification	Annex IV	
		thereof	EC declaration of	Annex II	
			conformity (full quality assurance system)	Annex V	
			EC declaration of conformity (production quality assurance) EC declaration of	Annex VI	
			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)			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

Name and address of the notified bodies	ID	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	quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		- *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants			

ι	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 Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives 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

Name and address of the notified bodies	ID	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	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
		medical devices - *MD 0102 - Non-active devices for injection, infusion,	conformity (full quality	Annex II Annex V Annex VI	exclusion medical devices class III
		medical devices	EC declaration of conformity (full quality	Annex II Annex V	exclusion medical devices class III
		- *MD 0103 - Non-active orthopaedic and rehabilitation	assurance system)	Annex VI	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	conformity (production quality assurance)  EC declaration of conformity (product quality assurance)  EC declaration of	Annex II	exclusion medical devices class III
		medical devices  - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)  EC declaration of conformity (product quality assurance)	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	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

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

EC verification

EC declaration of

conformity (full quality

assurance system)

EC declaration of conformity (production

Annex IV

Annex II

Annex V

Annex VI

- \*MD 1101 - Devices for extra-corporal circulation,

infusion and haemopheresis

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Annex IV	
			EC declaration of conformity (full quality assurance system)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)	Annex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1105 - Active ophthalmologic devices	EC verification	Annex IV	
			EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)	Alliex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1106 - Active dental devices	EC verification	Annex IV	
			EC declaration of conformity (full quality	Annex II Annex V	
			assurance system) EC declaration of	Annex VI	
			conformity (production		

Name and address of the notified bodies	ID	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	

### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives - \*MD 1109 - Active devices for patient positioning and EC verification Annex IV transport EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II conformity (full quality - \*MD 1111 - Software Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1200 - Devices for imaging EC type-examination Annex III - \*MD 1201 - Imaging devices utilising ionizing EC verification Annex IV radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance)

EC declaration of

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1202 - Imaging devices utilising non-ionizing	EC verification	Annex IV	
		radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)	Annex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	
		- *MD 1301 - Monitoring devices of non-vital	EC verification	Annex IV	
		physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)	Valliex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	
		- *MD 1302 - Monitoring devices of vital physiological parameters	EC verification EC declaration of	Annex IV Annex II	

### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo EC type-examination Annex III therapy EC verification Annex IV - \*MD 1401 - Devices utilising ionizing radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of

\*MD 1400 - Devices for radiation therapy and thermo

- \*MD 1402 - Devices utilising non-ionizing radiation

therapy

conformity (product quality

Annex III

Annex IV

Annex II

Annex V

Annex VI

EC type-examination

assurance)

EC verification

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance)
EC declaration of

conformity (full quality

Name and address of the notified bodies	ID	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	EC type-examination EC verification	Annex III Annex IV	
		- *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of	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	

Name and address of the notified bodies	ID	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)
Mit International Testing S.r.l. Via G.Leopardi, 14 20123 - Milano (MI) Italy	0068	*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software  *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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	assurance system)  EC declaration of conformity (production quality assurance)  EC declaration of conformity (product quality assurance)  EC declaration of	Annex VI Annex II	Excluding class III Medical Device
		- *MD 0401 - Non-active dental equipment and instruments		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	Excluding class III Medical Device
		*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 Device

Name and address of the notified bodies	ID	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)		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

Name and address of the notified bodies	ID	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

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives sterilisation conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Excluding class III Medical Devices Annex III - \*MD 1108 - Active rehabilitation devices and active EC verification Annex IV prostheses EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Excluding class III Medical Devices conformity (full quality - \*MD 1111 - Software Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of

conformity (product quality

assurance)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Med	ical 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 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 ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*MD 1302 - Monitoring devices of vital physiological conformity (full quality Annex V assurance system) parameters Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 1400 - Devices for radiation therapy and thermo Annex III Excluding class III Medical Devices therapy EC verification Annex IV - \*MD 1402 - Devices utilising non-ionizing radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo EC declaration of Annex II Excluding class III Medical Devices conformity (full quality therapy Annex V assurance system) - \*MD 1403 - Devices for hyperthermia / hypothermia Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality

assurance)

Name and address of the notified bodies	ID	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
BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom	0086	*MDS 7006 - Medical devices in sterile condition  *MDS 7010 - Medical devices incorporating software /utilising software /controlled by software  *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 for disinfecting, cleaning, rinsing	assurance	Annex II Annex III Annex IV Annex V Annex VI	

### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices ID Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) \*MD 0100 - General non-active, non-implantable EC type-examination Annex III medical devices EC verification Annex IV - \*MD 0110 - Non-active medical devices for ingestion EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) Full quality assurance \*MD 0200 - Non-active implants Annex II system - \*MD 0201 - Non-active cardiovascular implants Annex III EC type-examination - \*MD 0202 - Non-active orthopaedic implants Annex IV EC verification - \*MD 0203 - Non-active functional implants Annex V Production quality - \*MD 0204 - Non-active soft tissue implants Annex VI assurance \*MD 0300 - Devices for wound care Product quality assurance - \*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

## LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified Responsible for the following products Responsible for the **Limitations (English only)** ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*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 EC type-examination \*MD 1100 - General active medical devices Annex III - \*MD 1112 - Medical gas supply systems and parts EC verification Annex IV thereof EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of

conformity (production

Name and address of the notified bodies	ID	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	Full quality assurance system  EC type-examination  EC verification	Annex II Annex III Annex IV Annex V	
		radiation  *MD 1300 - Monitoring devices  - *MD 1301 - Monitoring devices of non-vital physiological parameters	Production quality assurance Product quality assurance	Annex VI	
		- *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 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			

Name and address of the notified bodies	ID	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	medical devices  - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	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			

Name and address of the notified bodies	ID	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			

Name and address of the notified bodies	ID	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	Full quality assurance system	Annex II Annex V	
		hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	
		- *MD 1103 - Devices for stimulation or inhibition	conformity (full quality assurance system)	Annex V Annex VI	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1104 - Active surgical devices	system Production quality assurance	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Product quality assurance Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Product quality assurance  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	

Name and address of the notified bodies	ID	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	system	Annex V	
		prostheses	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and	Full quality assurance	Annex II Annex V	
		transport	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1110 - Active devices for in vitro fertilisation	system	Annex V	
		(IVF) and assisted reproductive therapy (ART)	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1111 - Software	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1201 - Imaging devices utilising ionizing	system	Annex V	
		radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1202 - Imaging devices utilising non-ionizing	system	Annex V	
		radiation	Production quality	Annex VI	

Name and address of the notified bodies	ID	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	EC declaration of	Annex II	
		- *MD 1301 - Monitoring devices of non-vital	conformity (full quality	Annex V	
		physiological parameters	assurance system)	Annex VI	
			EC declaration of		
			conformity (production quality assurance)		
			EC declaration of		
			conformity (product quality assurance)		
		*MD 1300 - Monitoring devices	EC declaration of	Annex II	
		- *MD 1302 - Monitoring devices of vital physiological	conformity (full quality	Annex V	
		parameters	assurance system)	Annex VI	
			EC declaration of		
			conformity (production quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1401 - Devices utilising ionizing radiation	Production quality	Annex VI	
			assurance		
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1402 - Devices utilising non-ionizing radiation	Production quality		

Name and address of the notified bodies	ID	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	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1403 - Devices for hyperthermia / hypothermia	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0301 - Bandages and wound dressings	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0302 - Suture material and clamps	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		

Name and address of the notified bodies	ID	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,	system	Annex II Annex V Annex VI	
		emergency and intensive care	assurance Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	system	Annex II Annex V	
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	system	Annex II Annex V	
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0104 - Non-active medical devices with measuring function	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance	Annex II Annex V	
		- *MD 0105 - Non-active ophthalmologic devices	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance	Annex II Annex V	

Name and address of the notified bodies	ID	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	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

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0201 - Non-active cardiovascular implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	
		- *MD 0202 - Non-active orthopaedic implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	
		- *MD 0203 - Non-active functional implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0403 - Dental implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0401 - Non-active dental equipment and	system	Annex V	
		instruments	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0402 - Dental materials	system	Annex V	

Name and address of the notified bodies	ID	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	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion		Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	assurance system)	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			

Name and address of the notified bodies	ID	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	0400	*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
Ridlerstraße 65		- *MD 0301 - Bandages and wound dressings		Annex V	
80339 MÜNCHEN Germany	- *	- *MD 0302 - Suture material and clamps		Annex VI	
,		- *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	Full quality assurance	Annex II	
		- *MD 1101 - Devices for extra-corporal circulation,	system	Annex III	
		infusion and haemopheresis	EC type-examination	Annex IV	
			EC verification	Annex V	
		and acthoric	Production quality assurance	Annex VI	
		- *MD 1103 - Devices for stimulation or inhibition	Product quality assurance		
		- *MD 1104 - Active surgical devices			
		- *MD 1105 - Active ophthalmologic devices			
		- *MD 1106 - Active dental devices			

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified Responsible for the following products Responsible for the **Limitations (English only)** ID Annexes or following procedures /Horizontal technical competence articles of the or modules directives - \*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 EC type-examination Annex III - \*MD 1110 - Active devices for in vitro fertilisation EC verification Annex IV (IVF) and assisted reproductive therapy (ART) EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI

EC declaration of conformity (production quality assurance) EC declaration of

assurance)

system

\*MD 1200 - Devices for imaging

\*MD 1300 - Monitoring devices

physiological parameters

radiation

radiation

- \*MD 1201 - Imaging devices utilising ionizing

- \*MD 1301 - Monitoring devices of non-vital

- \*MD 1202 - Imaging devices utilising non-ionizing

- \*MD 1302 - Monitoring devices of vital physiological

conformity (product quality

Annex II

Annex III

Annex IV

Annex V

Annex VI

Full quality assurance

EC type-examination

EC verification

assurance

Production quality

Product quality assurance

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives 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 Full quality assurance Annex II medical devices system Annex V - \*MD 0103 - Non-active orthopaedic and rehabilitation Production quality Annex VI devices assurance - \*MD 0104 - Non-active medical devices with Product quality assurance 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 0100 - General non-active, non-implantable Full quality assurance Annex II

system

Annex III

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 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants  *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 verification Production quality assurance Product quality assurance Full quality assurance system Production quality assurance Product quality assurance EC type-examination EC verification	Annex IV Annex VI Annex II Annex VI Annex VI Annex III Annex IV Annex III Annex IV 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			

Name and address of the notified bodies	ID	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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		- *MD 0204 - Non-active soft tissue implants	Froduct quality assurance		

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*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 EC declaration of \*MD 1100 - General active medical devices Annex II conformity (full quality - \*MD 1101 - Devices for extra-corporal circulation, Annex V assurance system) infusion and haemopheresis Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices Full quality assurance Annex II system - \*MD 1102 - Respiratory devices, devices including Annex V hyperbaric chambers for oxygen therapy, inhalation Production quality Annex VI anaesthesia assurance Product quality assurance EC declaration of \*MD 1100 - General active medical devices Annex II conformity (full quality - \*MD 1103 - Devices for stimulation or inhibition Annex V assurance system) - \*MD 1104 - Active surgical devices Annex VI EC declaration of

- \*MD 1105 - Active ophthalmologic devices

	<u> </u>	or modules	articles of the directives	
	- *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	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives assurance Product quality assurance EC declaration of Annex II \*MD 1400 - Devices for radiation therapy and thermo conformity (full quality therapy Annex V assurance system) - \*MD 1402 - Devices utilising non-ionizing radiation Annex VI EC declaration of - \*MD 1403 - Devices for hyperthermia / hypothermia conformity (production - \*MD 1404 - Devices for (extracorporal) shock-wave quality assurance) therapy (lithotripsy) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II medical devices system Annex V Production quality - \*MD 0101 - Non-active devices for anaesthesia. Annex VI emergency and intensive care assurance - \*MD 0102 - Non-active devices for injection, infusion, Product quality assurance transfusion and dialysis - \*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

- \*MD 0104 - Non-active medical devices with

- \*MD 0105 - Non-active ophthalmologic devices

\*MD 0100 - General non-active, non-implantable

- \*MD 0107 - Contraceptive medical devices

- \*MD 0106 - Non-active instruments

measuring function

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. Consul and outing and implementable	conformity (production quality assurance)  EC declaration of conformity (product quality assurance)	Annu II	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Production quality assurance	Annex VI	
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Product quality assurance		
		*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	Annex II Annex V Annex VI	
			quality assurance) 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			Including aseptic processing,

Name and address of the notified bodies	ID	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			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 hicromechanics  *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	

Name and address of the notified bodies	ID	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	Annex III	
			EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0301 - Bandages and wound dressings	system	Annex V	
			Production quality	Annex VI	
			assurance		
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0302 - Suture material and clamps	system	Annex III	
			EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality	Annex VI	
			assurance		
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	
			Production quality	Annex VI	
			assurance		
		TAID 0400 Non-active dentity	Product quality assurance	A	
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0401 - Non-active dental equipment and	system  EC type examination	Annex III	
		instruments	EC type-examination	Annex IV	

Name and address of the notified bodies	ID	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	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system	Annex II Annex V	
		- *MD 0403 - Dental implants	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1109 - Active devices for patient positioning and transport	system EC type-examination	Annex III Annex IV	
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC verification Production quality	Annex V Annex VI	
		<ul> <li>*MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia</li> </ul>	assurance Product quality assurance		
		- *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)			

Name and address of the notified bodies	ID	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	Full quality assurance system	Annex II	
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	*	Annex V Annex VI	
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex III	
		- *MD 0104 - Non-active medical devices with measuring function	EC type-examination EC verification	Annex IV Annex V	
		- *MD 0105 - Non-active ophthalmologic devices	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0106 - Non-active instruments	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex III	
		- *MD 0107 - Contraceptive medical devices	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence articles of the or modules directives medical devices Annex V system - \*MD 0108 - Non-active medical devices for Production quality Annex VI disinfecting, cleaning, rinsing assurance - \*MD 0109 - Non-active devices for in vitro fertilisation Product quality assurance (IVF) and assisted reproductive technologies (ART) - \*MD 0101 - Non-active devices for anaesthesia. emergency and intensive care \*MD 1200 - Devices for imaging Full quality assurance Annex II system - \*MD 1201 - Imaging devices utilising ionizing Annex III radiation EC type-examination Annex IV - \*MD 1202 - Imaging devices utilising non-ionizing EC verification Annex V radiation Production quality Annex VI \*MD 1300 - Monitoring devices assurance

Product quality assurance

EC declaration of

conformity (full quality

Annex II

Annex V

Annex VI

- \*MD 1301 - Monitoring devices of non-vital

- \*MD 1302 - Monitoring devices of vital physiological

\*MD 1400 - Devices for radiation therapy and thermo

- \*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

\*MD 0100 - General non-active, non-implantable

- \*MD 0110 - Non-active medical devices for ingestion |assurance system)

physiological parameters

parameters

therapy (lithotripsy)

medical devices

therapy

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1112 - Medical gas supply systems and parts EC verification Annex IV thereof EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) 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 for active medical devices only 2006/42/EC on machinery Including aseptic processing, \*MDS 7006 - Medical devices in sterile condition ethylene oxide gas sterilisation

(EOG), moist heat sterilisation, radiation sterilisation (gamma,

Name and address of the notified bodies	ID	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	0297	*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
60433 FRANKFURT AM MAIN		- *MD 1201 - Imaging devices utilising ionizing	system	Annex V	
Germany		radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1202 - Imaging devices utilising non-ionizing	system	Annex V	
		radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1300 - Monitoring devices	Full quality assurance	Annex II	
		- *MD 1301 - Monitoring devices of non-vital	system	Annex V	
		physiological parameters	Production quality	Annex VI	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1302 - Monitoring devices of vital physiological	system	Annex V	
		parameters	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy	Full quality assurance system	Annex II Annex V	
		- *MD 1401 - Devices utilising ionizing radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	System  Draduation quality	Annex V	
		- *MD 1402 - Devices utilising non-ionizing radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0102 - Non-active devices for injection, infusion transfusion and dialysis	Production quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0402 - Dental materials	system	Annex V	
			Production quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0403 - Dental implants	system	Annex V	
			Production quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1104 - Active surgical devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1105 - Active ophthalmologic devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1106 - Active dental devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1107 - Active devices for disinfection and	system	Annex V	
		sterilisation	Production quality	Annex VI	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1108 - Active rehabilitation devices and active	system	Annex V	
		prostheses	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1109 - Active devices for patient positioning and	system	Annex V	
		transport	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1111 - Software	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1101 - Devices for extra-corporal circulation,	system	Annex V	
		infusion and haemopheresis	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1102 - Respiratory devices, devices including	system	Annex V	
		hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Production quality assurance	Annex VI	
			Product quality assurance		

Name and address of the notified bodies	ID	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	
		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 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	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	assurance)  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			

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1201 - Imaging devices utilising ionizing	EC verification	Annex IV	
		radiation	EC declaration of	Annex II	
		- *MD 1202 - Imaging devices utilising non-ionizing	conformity (full quality	Annex V	
		radiation	assurance system) EC declaration of	Annex VI	
		*MD 1300 - Monitoring devices	EC deciaration of		

Name and address of the notified bodies	ID	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 (production quality assurance)		
		- *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (product quality		
		*MD 1400 - Devices for radiation therapy and thermo therapy	assurance)		
		- *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	1		
		- *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	n		

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			
		- *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			
	1				

- \*MD 1110 - Active devices for in vitro fertilisation

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	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 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			

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 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				

Name and address of the notified bodies	ID	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			

Name and address of the notified bodies	ID	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	medical devices - *MD 0101 - Non-active devices for anaesthesia,	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		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	
		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	
		medical 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	
		*MD 0100 - General non-active, non-implantable	EC type-examination	Annex III	Annex III limited to ophthalmic

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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 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

Name and address of the notified bodies	ID	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	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	quality assurance)  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	

Name and address of the notified bodies	ID	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)

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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		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		Bone-anchored implants for denta 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	

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	
			EC declaration of conformity (production 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 declaration of conformity (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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

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

assurance)

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives EC type-examination \*MD 0100 - General non-active, non-implantable Annex III medical devices EC verification Annex IV - \*MD 0105 - Non-active ophthalmologic devices EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 0100 - General non-active, non-implantable Annex III medical devices EC verification Annex IV - \*MD 0106 - Non-active instruments EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC type-examination Annex III medical devices EC verification Annex IV

EC declaration of

assurance system)

conformity (full quality

Annex II

Annex V

Annex VI

- \*MD 0107 - Contraceptive medical devices

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC type-examination Annex III medical devices EC verification Annex IV - \*MD 0108 - Non-active medical devices for EC declaration of Annex II disinfecting, cleaning, rinsing conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC type-examination Annex III medical devices EC verification Annex IV - \*MD 0109 - Non-active devices for in vitro fertilisation EC declaration of Annex II (IVF) and assisted reproductive technologies (ART) conformity (full quality Annex V assurance system) Annex VI EC declaration of

conformity (production quality assurance)

EC declaration of

conformity (product quality

assurance)

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives EC type-examination \*MD 0200 - Non-active implants Annex III - \*MD 0202 - Non-active orthopaedic implants EC verification Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination neurological and neurosurgical \*MD 0200 - Non-active implants Annex III implants excluded EC verification Annex IV - \*MD 0203 - Non-active functional implants EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0300 - Devices for wound care EC type-examination Annex III EC verification - \*MD 0301 - Bandages and wound dressings Annex IV EC declaration of Annex II conformity (full quality Annex V

assurance system)

Annex VI

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or /Horizontal technical competence following procedures bodies articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0300 - Devices for wound care EC type-examination Annex III EC verification - \*MD 0302 - Suture material and clamps Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 0300 - Devices for wound care Annex III - \*MD 0303 - Other medical devices for wound care EC verification Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of

conformity (product quality

assurance)

L	IST 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	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	
			EC declaration of 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	
		*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	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1101 - Devices for extra-corporal circulation, EC verification Annex IV infusion and haemopheresis EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1102 - Respiratory devices, devices including EC verification Annex IV hyperbaric chambers for oxygen therapy, inhalation EC declaration of Annex II anaesthesia conformity (full quality Annex V assurance system) Annex VI

EC declaration of conformity (production quality assurance)
EC declaration of

assurance)

conformity (product quality

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives EC type-examination \*MD 1100 - General active medical devices Annex III - \*MD 1103 - Devices for stimulation or inhibition EC verification Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 1100 - General active medical devices Annex III EC verification Annex IV - \*MD 1104 - Active surgical devices EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III EC verification - \*MD 1105 - Active ophthalmologic devices Annex IV EC declaration of Annex II conformity (full quality Annex V

assurance system)

Annex VI

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or /Horizontal technical competence following procedures bodies articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III EC verification - \*MD 1106 - Active dental devices Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 1100 - General active medical devices Annex III - \*MD 1107 - Active devices for disinfection and EC verification Annex IV sterilisation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of

conformity (product quality

assurance)

ι	IST 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	EC type-examination	Annex III	
		- *MD 1108 - Active rehabilitation devices and active	EC verification	Annex IV	
		prostheses	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	
			EC declaration of conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1109 - Active devices for patient positioning and	EC verification	Annex IV	
		transport	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	
			EC declaration of		
			conformity (production quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1110 - Active devices for in vitro fertilisation	EC verification	Annex IV	
		(IVF) and assisted reproductive therapy (ART)	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or /Horizontal technical competence following procedures bodies articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III EC verification - \*MD 1111 - Software Annex IV EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1200 - Devices for imaging EC type-examination Annex III - \*MD 1201 - Imaging devices utilising ionizing EC verification Annex IV radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of

conformity (product quality

assurance)

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives EC type-examination \*MD 1200 - Devices for imaging Annex III - \*MD 1202 - Imaging devices utilising non-ionizing EC verification Annex IV radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 1300 - Monitoring devices Annex III EC verification - \*MD 1301 - Monitoring devices of non-vital Annex IV physiological parameters EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1300 - Monitoring devices EC type-examination Annex III - \*MD 1302 - Monitoring devices of vital physiological EC verification Annex IV parameters EC declaration of Annex II conformity (full quality Annex V

assurance system)

Annex VI

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo EC type-examination Annex III therapy EC verification Annex IV - \*MD 1401 - Devices utilising ionizing radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo EC type-examination Annex III therapy EC verification Annex IV - \*MD 1402 - Devices utilising non-ionizing radiation EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality

assurance)

	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	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)	assurance)  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

Name and address of the notified bodies	ID	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	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	
		medical devices - *MD 0102 - Non-active devices for injection, infusion,	assurance	Annex II Annex V Annex VI	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*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 EC declaration of Annex II conformity (full quality - \*MD 1101 - Devices for extra-corporal circulation, Annex V assurance system) infusion and haemopheresis Annex VI EC declaration of - \*MD 1102 - Respiratory devices, devices including conformity (production hyperbaric chambers for oxygen therapy, inhalation

anaesthesia

quality assurance)

### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified Responsible for the following products Responsible for the **Limitations (English only)** ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*MD 1103 - Devices for stimulation or inhibition EC declaration of conformity (product quality - \*MD 1104 - Active surgical devices assurance) - \*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

ICIM S.P.A.

Italy

Piazza Don Enrico Mapelli, 75

20099 - Sesto San Giovanni (MI)

**bodies** 

medical devices

medical devices

measuring function

transfusion and dialysis

- \*MD 0102 - Non-active devices for injection, infusion,

\*MD 0100 - General non-active, non-implantable

- \*MD 0104 - Non-active medical devices with

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives \*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery \*MDS 7006 - Medical devices in sterile condition 0425 \*MD 0100 - General non-active, non-implantable EC declaration of Annex II Exclusion of class III medical medical devices conformity (full quality devices Annex V assurance system) - \*MD 0101 - Non-active devices for anaesthesia, Annex VI emergency and intensive care EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC declaration of Annex II Exclusion of class III medical

conformity (full quality

conformity (production quality assurance) EC declaration of

conformity (product quality

assurance system)

EC declaration of

assurance)

EC declaration of

conformity (full quality

assurance system)

EC declaration of conformity (production quality assurance) EC declaration of

devices

devices

Exclusion of class III medical

Annex V

Annex VI

Annex II

Annex V

Annex VI

Name and address of the notified bodies	ID	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)		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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Exclusion of class III medical devices
			EC declaration of conformity (production quality assurance)	, uniox vi	
			EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	Exclusion of class III medical
		- *MD 0303 - Other medical devices for wound care	conformity (full quality assurance system)	Annex V Annex VI	devices
			EC declaration of conformity (production 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)	Annex II Annex V Annex VI	Exclusion of class III medical devices
			EC declaration of conformity (production quality assurance)	,	
			EC declaration of conformity (product quality assurance)		

L	IST 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 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

Name and address of the notified bodies	ID	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	Annex V Annex VI	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	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices
			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	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III 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	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 ar

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)		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 V Annex VI	Exclusion of class III medical devices, except surgically device intended for transient use, in dire 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		Exclusion of class III 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		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	assurance)  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)  EC declaration of conformity (product quality assurance)		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)		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		Exclusion of class III 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 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

Name and address of the notified bodies	ID	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)		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

Name and address of the notified bodies	ID	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)		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

bodies

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products /Horizontal technical competence **Limitations (English only)** Responsible for the Annexes or

	/Horizontal technical competence	following procedures or modules	articles of the directives	
ſ		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

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 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	

EC declaration of

Annex II

\*MD 1100 - General active medical devices

Exclusion of class III medical

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	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

Name and address of the notified bodies	ID	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,	assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*MD 0100 - General non-active, non-implantable EC type-examination Annex III medical devices EC verification Annex IV - \*MD 0110 - Non-active medical devices for ingestion |EC declaration of Annex II \*MD 0200 - Non-active implants conformity (full quality Annex V assurance system) - \*MD 0201 - Non-active cardiovascular implants Annex VI EC declaration of - \*MD 0202 - Non-active orthopaedic implants conformity (production - \*MD 0203 - Non-active functional implants quality assurance) - \*MD 0204 - Non-active soft tissue implants EC declaration of \*MD 0300 - Devices for wound care conformity (product quality - \*MD 0301 - Bandages and wound dressings assurance) - \*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

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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 EC type-examination Annex III Annex II - \*MD 1111 - Software EC declaration of conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1112 - Medical gas supply systems and parts EC verification Annex IV thereof EC declaration of Annex II \*MD 1200 - Devices for imaging conformity (full quality Annex V assurance system) - \*MD 1201 - Imaging devices utilising ionizing Annex VI

EC declaration of conformity (production

quality assurance)

radiation

radiation

- \*MD 1202 - Imaging devices utilising non-ionizing

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*MD 1300 - Monitoring devices EC declaration of conformity (product quality - \*MD 1301 - Monitoring devices of non-vital assurance) 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 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

\*MDS 7007 - Medical devices utilising micromechanics

\*MDS 7008 - Medical devices utilising nanomaterials

Chemical sterilization/Dry heat sterilization/Hydrogen peroxid with

Temperature Infusion sterilization

or without plasma process sterilization/Ultra High

process

Name and address of the notified bodies	ID	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	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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 0303 - Other medical devices for wound care	assurance)  EC declaration of conformity (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 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 V	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Excluding class III medical devices
			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)	Annex II Annex V Annex VI	Excluding class III medical devices
			EC declaration of 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)	Annex V	Excluding class III medical devices
			EC declaration of conformity (production	Annex VI	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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 V	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

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

\*MD 1100 - General active medical devices

- \*MD 1111 - Software

\*MD 1200 - Devices for imaging

- \*MD 1202 - Imaging devices utilising non-ionizing

conformity (product quality

Annex II

Annex V

Annex VI

Annex II

Annex V

assurance)

assurance)

EC declaration of conformity (full quality

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance)
EC declaration of

conformity (full quality

conformity (product quality

Excluding class III medical devices

Excluding class III medical devices

and devices for magnetic

Name and address of the notified bodies	ID	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	Annex VI	resonance
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	assurance)  EC declaration of conformity (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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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 device
		*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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	assurance)  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

Name and address of the notified bodies	ID	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	assurance system)  EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
			quality assurance) EC declaration of conformity (product quality assurance)		
		*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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	Excluding class III medical devices
		- *MD 0402 - Dental materials	EC verification	Annex IV	
			EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories	EC type-examination	Annex III	Excluding class III medical devices
		- *MD 0403 - Dental implants	EC verification	Annex IV	
			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	
		**************************************	assurance)		_ , , , , , , , , , , ,
		*MD 1100 - General active medical devices	EC declaration of conformity (full quality		Excluding class III medical devices
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	assurance system)  EC declaration of	Annex V Annex VI	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

**bodies** 

transport

\*MD 1100 - General active medical devices

- \*MD 1111 - Software

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Excluding class III medical devices conformity (full quality - \*MD 1108 - Active rehabilitation devices and active Annex V assurance system) prostheses Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of \*MD 1100 - General active medical devices Annex II Excluding class III medical devices - \*MD 1109 - Active devices for patient positioning and conformity (full quality Annex V

assurance system)

conformity (product quality

EC declaration of conformity (production quality assurance) EC declaration of

assurance)

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance) EC declaration of

conformity (full quality

Annex VI

Annex II

Annex V

Annex VI

Excluding class III 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 N	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)	Annex II Annex V Annex VI	Excluding class III medical devices
			EC declaration of conformity (production 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)	Annex II Annex V Annex VI	Excluding class III medical devices
			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	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices
		therapy (lithotripsy)	EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		

Name and address of the notified bodies	ID	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		Full quality assurance system EC type-examination Production quality	Annex II Annex III Annex V Annex VI	Only stents, implantable catheters, vascular grafts, occlusion systems
			assurance Product quality assurance		
			Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
			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	

Name and address of the notified bodies	ID	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	system	Annex V	
		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex III	Annex III: Only infusion sets, transfusion sets, catheters, tubing systems for extra-corporal
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination Production quality assurance	Annex V Annex VI	circulation
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Production quality assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices	system	Annex V	
		- *MD 0104 - Non-active medical devices with measuring function	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices - *MD 0105 - Non-active ophthalmologic devices	system Production quality assurance	Annex V Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0401 - Non-active dental equipment and	system	Annex V	
		instruments	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0402 - Dental materials	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0403 - Dental implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	
		- *MD 0110 - Non-active medical devices for ingestion	assurance system)  EC declaration of conformity (production	Annex VI	
			quality assurance)		

Name and address of the notified bodies	ID	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 V	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

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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  *MD 0100 - General non-active, non-implantable medical devices  - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI  Annex III Annex II Annex V Annex V	
		*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 (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	
			quality assurance)  EC declaration of conformity (product quality assurance)		
		*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	
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants	EC type-examination	Annex III	
		- *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production		

Name and address of the notified bodies	ID	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	Annex II Annex V Annex VI	

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

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 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					

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1401 - Devices utilising ionizing radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	
		therapy	system	Annex V	
		- *MD 1402 - Devices utilising non-ionizing radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices	system	Annex V	
		- *MD 0107 - Contraceptive medical devices	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0108 - Non-active medical devices for	Production quality	Annex VI	
		disinfecting, cleaning, rinsing	assurance Product quality assurance		

Name and address of the notified bodies	ID	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	system	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		Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Dan desetion over liter	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance	Annex II Annex V	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1106 - Active dental devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy	EC declaration of conformity (full quality	Annex II Annex V	
		- *MD 1403 - Devices for hyperthermia / hypothermia	assurance system) EC declaration of conformity (production	Annex VI	
			quality assurance)  EC declaration of conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	assurance)		
		*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

Name and address of the notified bodies	ID	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		excluding class III devices (valid for the complete scope)

Name and address of the notified bodies	ID	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	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	excluding class III devices (valid for
		- *MD 1105 - Active ophthalmologic devices	system	Annex III	the complete scope)
			EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	excluding class III devices (valid for
		- *MD 1106 - Active dental devices	system	Annex III	the complete scope)
			EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	EC type-examination		excluding class III devices (valid for
		- *MD 1112 - Medical gas supply systems and parts	EC verification	Annex IV	the complete scope)
		thereof	EC declaration of	Annex II	
				Annex V	
			assurance system)	Annex VI	
			EC declaration of conformity (production		
			quality assurance)		

Name and address of the notified bodies	ID	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	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	Product quality assurance Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance		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)

Name and address of the notified bodies	ID	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	Annex IV	
			Production quality	Annex V	
			assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	excluding class III devices (valid for
		- *MD 1202 - Imaging devices utilising non-ionizing	system	Annex III	the complete scope)
		radiation	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality	Annex VI	
			assurance		
			Product quality assurance		
		*MD 1300 - Monitoring devices	Full quality assurance	Annex II	excluding class III devices (valid for
		- *MD 1301 - Monitoring devices of non-vital	system	Annex III	the complete scope)
		physiological parameters	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1300 - Monitoring devices	Full quality assurance	Annex II	excluding class III devices (valid for
		- *MD 1302 - Monitoring devices of vital physiological	system	Annex III	the complete scope)
		parameters	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality		
			assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	excluding class III devices (valid for

Name and address of the notified bodies	ID	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	system	Annex III	the complete scope)
		- *MD 1401 - Devices utilising ionizing radiation	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy	Full quality assurance system		excluding class III devices (valid for the complete scope)
		- *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy	Full quality assurance system		excluding class III devices (valid for the complete scope)
		- *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination	Annex IV	
			EC verification	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*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 ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives Annex VI - \*MD 0101 - Non-active devices for anaesthesia. EC declaration of conformity (production emergency and intensive care quality assurance) EC declaration of conformity (product quality assurance) \*MD 0200 - Non-active implants EC declaration of Annex II Excluding class III conformity (full quality - \*MD 0202 - Non-active orthopaedic implants Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0300 - Devices for wound care EC declaration of Annex II Excluding class III conformity (full quality - \*MD 0301 - Bandages and wound dressings Annex V assurance system) Annex VI EC declaration of conformity (production

\*MD 0400 - Non-active dental devices and accessories

- \*MD 0401 - Non-active dental equipment and

instruments

quality assurance)
EC declaration of

assurance)

EC declaration of

conformity (full quality

assurance system)

EC declaration of

conformity (product quality

Annex II

Annex V

Annex VI

Excluding class III

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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		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	conformity (full quality	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	conformity (full quality	Annex II Annex V Annex VI	Excluding class III

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

\*MD 0400 - Non-active dental devices and accessories

- \*MD 0402 - Dental materials

assurance)

EC declaration of

conformity (full quality

conformity (product quality

assurance system)

EC declaration of conformity (production quality assurance)
EC declaration of

Excluding class III

Annex II

Annex V

Annex VI

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives assurance) EC declaration of Annex II Excluding class III \*MD 0400 - Non-active dental devices and accessories conformity (full quality - \*MD 0403 - Dental implants Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Excluding class III conformity (full quality - \*MD 1104 - Active surgical devices Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) Excluding class III \*MD 1100 - General active medical devices EC declaration of Annex II conformity (full quality - \*MD 1105 - Active ophthalmologic devices Annex V assurance system) Annex VI EC declaration of

conformity (production quality assurance)

EC declaration of

conformity (product quality

assurance)

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	assurance)  EC declaration of conformity (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		Excluding orthopaedic implants re 2005/50/EEC and bone cement

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Alliez 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	

Name and address of the notified bodies	ID	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  *MD 1200 - Devices for imaging	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of conformity (product quality assurance) EC declaration of	Annex II Annex V Annex VI	
		- *MD 1201 - Imaging devices utilising ionizing radiation	conformity (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	

Name and address of the notified bodies	ID	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			

Name and address of the notified bodies	ID	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	Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according t Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly o mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices  - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	assurance)  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production	Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according t Directive 2001/83/EC and/or

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating
			EC declaration of conformity (production quality assurance)		medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings
			EC declaration of conformity (product quality assurance)		and/or materials or being wholly or mainly absorbed
		*MD 0400 - Non-active dental devices and accessories	EC declaration of	Annex II	Exclusion of class III medical
		- *MD 0401 - Non-active dental equipment and instruments	conformity (full quality assurance system)	Annex V Annex VI	devices
			EC declaration of conformity (production quality assurance)	Annex VI	
			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)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating
			EC declaration of conformity (production quality assurance)		medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings
			EC declaration of conformity (product quality assurance)		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 Responsible for the following products **Limitations (English only)** ID Responsible for the Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*MD 0400 - Non-active dental devices and accessories EC declaration of Annex II Exclusion of class III medical conformity (full quality devices, except those classified in - \*MD 0403 - Dental implants Annex V assurance system) class III only as incorporating Annex VI medicinal substances, according to EC declaration of Directive 2001/83/EC and/or conformity (production utilising biological active coatings quality assurance) and/or materials or being wholly or EC declaration of mainly absorbed conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Excluding hyperbaric chambers conformity (full quality and all devices depending on a - \*MD 1102 - Respiratory devices, devices including Annex V source of electrical energy. assurance system) hyperbaric chambers for oxygen therapy, inhalation Annex VI Exclusion of class III medical anaesthesia EC declaration of devices, except those classified in conformity (production Class III only as incorporating quality assurance) medicinal substances, according to EC declaration of Directive 2001/83/EC conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Exclusion of class III medical conformity (full quality devices - \*MD 1111 - Software Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)

EC declaration of

Annex II

\*MD 1400 - Devices for radiation therapy and thermo

Excluding 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 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			

Name and address of the notified bodies	ID	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	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
		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
		medical devices - *MD 0104 - Non-active medical devices with	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	II: Up to class IIb only

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

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

conformity (product quality

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	II: Up to class IIb only; III, IV: X-ray
		- *MD 1201 - Imaging devices utilising ionizing	EC verification	Annex IV	devices only
		radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)	, uniox vi	
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging	EC type-examination	Annex III	II: Up to class IIb only; III, IV:
		- *MD 1202 - Imaging devices utilising non-ionizing	EC verification	Annex IV	Magnetic resonance imaging (MRI)
		radiation	EC declaration of	Annex II	devices only
			conformity (full quality assurance system)  EC declaration of	Annex V Annex VI	
			conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	II: Up to class IIb only
		- *MD 1301 - Monitoring devices of non-vital	EC verification	Annex IV	
		physiological parameters	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 ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1300 - Monitoring devices EC type-examination Annex III II: Up to class IIb only - \*MD 1302 - Monitoring devices of vital physiological EC verification Annex IV parameters EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo II: Up to class IIb only EC declaration of Annex II

therapy

- \*MD 1401 - Devices utilising ionizing radiation

\*MD 1400 - Devices for radiation therapy and thermo

conformity (full quality

conformity (product quality

EC type-examination

assurance system)

EC declaration of conformity (production quality assurance)
EC declaration of

assurance)

Annex V

Annex VI

Annex III

II: Up to class IIb only; III, IV:

Name and address of the notified bodies	ID	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	EC verification	Annex IV	Surgical ultrasoud devices only
		- *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 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	

Name and address of the notified bodies

Name and address of the notified bodies	ID	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	0636	*MD 1100 - General active medical devices	EC type-examination	Annex III	
Kopernikusgasse 24/1		•	EC verification	Annex IV	
8010 GRAZ Austria			EC declaration of	Annex II	
		1		Annex V	
			assurance system) EC declaration of	Annex VI	
			conformity (production		
			quality assurance) EC declaration of conformity (product quality assurance)		
		_			
		- *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			

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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

\*MDS 7006 - Medical devices in sterile condition

2006/42/EC on machinery

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A EKAPTY Smyrnis 15 165 62 GLYFADA Greece	0653	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	
		medical devices  - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	conformity (full quality	Annex II Annex V Annex VI	
		medical devices  - *MD 0103 - Non-active orthopaedic and rehabilitation devices	conformity (full quality	Annex II Annex V Annex VI	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	assurance system)  EC declaration of conformity (production quality assurance)  EC declaration of conformity (product quality assurance)  EC declaration of	Annex VI Annex II	
		- *MD 0302 - Suture material and clamps	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 declaration of conformity (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 ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0400 - Non-active dental devices and accessories EC declaration of Annex II conformity (full quality - \*MD 0402 - Dental materials Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0400 - Non-active dental devices and accessories EC declaration of Annex II conformity (full quality - \*MD 0403 - Dental implants Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II conformity (full quality - \*MD 1101 - Devices for extra-corporal circulation, Annex VI assurance system) infusion and haemopheresis

EC declaration of

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Respiratory devices only conformity (full quality - \*MD 1102 - Respiratory devices, devices including Annex VI assurance system) hyperbaric chambers for oxygen therapy, inhalation anaesthesia EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II Only for physiotherapy conformity (full quality - \*MD 1103 - Devices for stimulation or inhibition Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II conformity (full quality - \*MD 1104 - Active surgical devices Annex V assurance system) EC declaration of conformity (production quality assurance) EC declaration of \*MD 1100 - General active medical devices Annex II

- \*MD 1106 - Active dental devices

conformity (full quality

assurance system)

EC declaration of conformity (production

Annex V

Annex VI

Name and address of the notified bodies	ID	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	

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

\*MD 1400 - Devices for radiation therapy and thermo

- \*MD 1403 - Devices for hyperthermia / hypothermia

therapy

EC declaration of

EC declaration of

conformity (full quality

conformity (product quality

assurance system)

EC declaration of conformity (production quality assurance)
EC declaration of

assurance)

conformity (product quality

Annex II

Annex V

Annex VI

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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		excluding class III devices (valid for the complete scope)

Name and address of the notified bodies	ID	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)

Name and address of the notified bodies	ID	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	quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

L	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							

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
UL INTERNATIONAL (UK) LTD Wonersh House Building C The Guildway Old Portsmouth Road Guildford GU3 1LR United Kingdom	0843	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  *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)	/ IIIICX V	Limited to sterile single use devices and surgical instruments, class IIb and below

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Class IIb and below
			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)		Limited to sterile single use devices, class IIb and below
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	Class IIb and below
		- *MD 0302 - Suture material and clamps	conformity (full quality assurance system)	Annex V Annex VI	
			EC declaration of conformity (production		

Name and address of the notified bodies	ID	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		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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	No class III or implants		
			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)	Annex II Annex V Annex VI	No class III or implants		
			EC declaration of conformity (product quality 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)	Annex II Annex V Annex VI	No class III or implants		

conformity (product quality

Name and address of the notified bodies	ID	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	Annex II Annex V Annex VI	No class III or implants
			quality assurance) EC declaration of conformity (product quality assurance)		
		*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	Annex II Annex V Annex VI	No class III or implants
			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	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	No class III or implants
		anaesthesia	EC declaration of conformity (production quality assurance)		

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC declaration of Annex II No class III or implants conformity (full quality - \*MD 1103 - Devices for stimulation or inhibition Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)

Name and address of the notified bodies	ID	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

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

\*MD 1300 - Monitoring devices

quality assurance)
EC declaration of

EC type-examination

assurance)

conformity (product quality

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				

Name and address of the notified bodies	ID	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	EC type-examination EC declaration of	Annex III Annex II	
		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex V Annex VI	
			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 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	

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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 II Annex V	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	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	

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of \*MD 0400 - Non-active dental devices and accessories Annex II conformity (full quality - \*MD 0402 - Dental materials Annex V assurance system)

EC declaration of conformity (production quality assurance) EC declaration of

assurance)

\*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,

conformity (product quality

EC type-examination

conformity (full quality

conformity (product quality

EC type-examination

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance) EC declaration of

assurance)

EC declaration of

Annex VI

Annex III

Annex II

Annex V

Annex VI

Annex III

Annex II

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence bodies articles of the or modules directives infusion and haemopheresis conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1102 - Respiratory devices, devices including EC declaration of Annex II hyperbaric chambers for oxygen therapy, inhalation conformity (full quality Annex V anaesthesia assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices EC type-examination Annex III - \*MD 1103 - Devices for stimulation or inhibition EC declaration of Annex II conformity (full quality Annex V

assurance system)

conformity (product quality

EC declaration of conformity (production quality assurance)
EC declaration of

assurance)

Annex VI

Name and address of the notified bodies	ID	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)	Annex III Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance) EC declaration of		
		*MD 1100 - General active medical devices	conformity (product quality assurance)  EC type-examination	Annex III	
		- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			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 declaration of conformity (full quality assurance system)	Annex III Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)  EC declaration of		

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC type-examination	Annex III	
		- *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production		

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives Annex VI assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0300 - Devices for wound care EC type-examination Annex III - \*MD 0302 - Suture material and clamps EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of

conformity (product quality

assurance)

2006/42/EC on machinery

\*MDS 7006 - Medical devices in sterile condition

conformity (production quality assurance) EC declaration of

Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives 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, 1014 \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II medical devices system Annex V Pod Lisem 129 171 02 PRAHA 71 - Troia - \*MD 0101 - Non-active devices for anaesthesia. Production quality Annex VI Czech Republic emergency and intensive care assurance - \*MD 0102 - Non-active devices for injection, infusion, Product quality assurance 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 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 0107 - Contraceptive medical devices\*MD 0108 - Non-active medical devices for

- \*MD 0106 - Non-active instruments

disinfecting, cleaning, rinsing \*MD 0200 - Non-active 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 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 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	EC type-examination	Annex III	
		- *MD 1112 - Medical gas supply systems and parts	EC verification	Annex IV	
		thereof	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	
			EC declaration of conformity (production		
			quality assurance)		
			EC declaration of		
				1	

conformity (product quality

Name and address of the notified bodies	ID	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	conformity (full quality	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	assurance) EC declaration of	Annex II	Limited to devices of Classes Im,

Name and address of the notified bodies	ID	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	ls, 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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	, uniox v	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 V Annex VI	Limited to devices of the Class III plus injection implants based on hyaluronic acid and hyaluronic ac 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 V Annex VI	Limited to devices of Classes Is, IIa, IIb plus wound dressing being wholly or mainly absorbed and/or incorporating medicinal substance

Name and address of the notified bodies	ID	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	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
			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)	Annex II Annex V Annex VI	Limited to devices of Classes Is, Ila, Ilb plus wound care devices being wholly or mainly absorbed
			EC declaration of conformity (production quality assurance)		and/or incorporating medicinal substances
			EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories	EC declaration of		Limited to devices of Classes Im,
		- *MD 0401 - Non-active dental equipment and instruments	conformity (full quality assurance system)	Annex V Annex VI	ls, IIa, IIb
			EC declaration of conformity (production		

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Limited to devices of Classes Im,
		- *MD 1111 - Software	conformity (full quality assurance system)	Annex V Annex VI	lla, llb
			EC declaration of 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)	Annex II Annex V Annex VI	Limited to devices of Classes Im, Is, IIa, IIb
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*MD 1200 - Devices for imaging EC declaration of Annex II imited to devices of Classes Im. conformity (full quality ls. IIa. IIb - \*MD 1202 - Imaging devices utilising non-ionizing Annex V assurance system) radiation Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of \*MD 1300 - Monitoring devices Annex II imited to devices of Classes Im. conformity (full quality ls, Ila, Ilb - \*MD 1302 - Monitoring devices of vital physiological Annex V assurance system) parameters Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC declaration of imited to devices of Classes Im. \*MD 1400 - Devices for radiation therapy and thermo Annex II conformity (full quality therapy ls, Ila, Ilb Annex V assurance system) - \*MD 1402 - Devices utilising non-ionizing radiation Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality

\*MD 1400 - Devices for radiation therapy and thermo

assurance)

EC declaration of

Annex II

Limited to devices of Classes Im.

Name and address of the notified bodies	ID	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	Annex II Annex V Annex VI		

Name and address of the notified bodies	ID	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	Full quality assurance system	Annex II Annex V	
		- *MD 0104 - Non-active medical devices with measuring function	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0105 - Non-active ophthalmologic devices	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0106 - Non-active instruments	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices	system	Annex V	
		- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	
		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Production quality assurance	Annex VI	
			Product quality assurance		

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0202 - Non-active orthopaedic implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	
		- *MD 0203 - Non-active functional implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	
		- *MD 0204 - Non-active soft tissue implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0301 - Bandages and wound dressings	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0302 - Suture material and clamps	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1103 - Devices for stimulation or inhibition	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1104 - Active surgical devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1105 - Active ophthalmologic devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1106 - Active dental devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1107 - Active devices for disinfection and	system	Annex V	
		sterilisation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

Name and address of the notified bodies	ID	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	system	Annex V	
		prostheses	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing	Full quality assurance system	Annex II Annex V	
		radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1202 - Imaging devices utilising non-ionizing radiation	system Production quality assurance	Annex V Annex VI	
			Product quality assurance		
		*MD 1400 - Devices for radiation therapy and thermo therapy	Full quality assurance system	Annex II Annex V	
		- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Production quality assurance	Annex VI	
			Product quality assurance		
		*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	1254	*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	Single-use medical devices
Switzerland		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Production quality assurance	Annex VI	
			Product quality assurance		

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified Responsible for the following products Responsible for the **Limitations (English only)** ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II Single-use medical devices medical devices system Annex V - \*MD 0102 - Non-active devices for injection, infusion, Production quality Annex VI transfusion and dialysis assurance Product quality assurance \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II medical devices system Annex V - \*MD 0103 - Non-active orthopaedic and rehabilitation Production quality Annex VI devices assurance Product quality assurance \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II Reusable instruments medical devices system Annex V - \*MD 0104 - Non-active medical devices with Production quality Annex VI measuring function assurance Product quality assurance \*MD 0100 - General non-active, non-implantable Full quality assurance Single-use medical devices Annex II medical devices system Annex V - \*MD 0105 - Non-active ophthalmologic devices Production quality Annex VI assurance Product quality assurance \*MD 0100 - General non-active, non-implantable Full quality assurance Annex II medical devices system Annex V - \*MD 0106 - Non-active instruments Production quality Annex VI assurance Product quality assurance Full quality assurance \*MD 0100 - General non-active, non-implantable Annex II Single-use medical devices

system

Annex V

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	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	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0303 - Other medical devices for wound care	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0401 - Non-active dental equipment and	system	Annex V	
		instruments	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0402 - Dental materials	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	
		- *MD 0403 - Dental implants	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1106 - Active dental devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*MD 1109 - Active devices for patient positioning and system Annex V transport Production quality Annex VI assurance Product quality assurance \*MD 1200 - Devices for imaging Full quality assurance Annex II system - \*MD 1202 - Imaging devices utilising non-ionizing Annex V radiation Production quality Annex VI assurance Product quality assurance \*MD 1300 - Monitoring devices Full quality assurance Annex II system - \*MD 1301 - Monitoring devices of non-vital Annex V physiological parameters Production quality Annex VI assurance Product quality assurance \*MD 0100 - General non-active, non-implantable EC declaration of Annex II conformity (full quality medical devices Annex V - \*MD 0110 - Non-active medical devices for ingestion |assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality

\*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

assurance)

Name and address of the notified bodies	ID	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	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
		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

# LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices d ID Responsible for the following products Responsible for the Annexes or Limit

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*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	6 26 76 11 124	Annex III Annex IV Annex II Annex V Annex VI	Annex III and IV lasers only
		Wild Trot Boylood for extra corporar or calation,	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	Annex III Annex IV	Annex III and IV lasers only		

EC declaration of

Annex II

**bodies** 

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the or modules directives conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1100 - General active medical devices Full quality assurance Annex II system - \*MD 1107 - Active devices for disinfection and Annex V Production quality sterilisation Annex VI assurance Product quality assurance

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance) EC declaration of

assurance)

EC declaration of

assurance system)

EC declaration of conformity (production quality assurance)

conformity (full quality

conformity (product quality

Annex II

Annex V

Annex VI

Annex II

Annex V

Annex VI

\*MD 1100 - General active medical devices

\*MD 1100 - General active medical devices

- \*MD 1109 - Active devices for patient positioning and conformity (full quality

- \*MD 1111 - Software

transport

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	EC type-examination	Annex III	
		- *MD 1301 - Monitoring devices of non-vital	EC verification	Annex IV	
		physiological parameters	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	
			EC declaration of conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	
		- *MD 1302 - Monitoring devices of vital physiological	EC verification	Annex IV	
		parameters	EC declaration of	Annex II	
			conformity (full quality	Annex V	
			assurance system)	Annex VI	
			EC declaration of conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 0400 - Non-active dental devices and accessories	EC declaration of	Annex II	
		- *MD 0401 - Non-active dental equipment and	conformity (full quality	Annex V	
		instruments	assurance system)	Annex VI	
			EC declaration of		

Name and address of the notified bodies	ID	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	conformity (production quality assurance)  EC declaration of conformity (product quality assurance)  EC declaration of	Annex II	
		- *MD 1201 - Imaging devices utilising ionizing radiation	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 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	

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

therapy

- \*MD 1402 - Devices utilising non-ionizing radiation

conformity (full quality

assurance system)

EC declaration of conformity (production quality assurance)

Annex V

Annex VI

Name and address of the notified bodies	ID	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)		
		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	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	Annex II Annex V Annex VI	Excluding class III medical devices
		, .	assurance)  EC declaration of conformity (full quality	Annex II Annex V	Excluding class III 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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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 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

Name and address of the notified bodies	ID	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	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	assurance)  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
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	conformity (product quality assurance)  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

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Excluding class III medical devices
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices	EC declaration of	Annex II	Excluding class III medical devices
		- *MD 1302 - Monitoring devices of vital physiological parameters	conformity (full quality assurance system)	Annex V Annex VI	
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		
		*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
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		

Name and address of the notified bodies	ID	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 device
		*MDS 7006 - Medical devices in sterile condition			Excluding class III medical device
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.  II. Klobucka 23A 102-699 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 0203 - Non-active orthopaedic implants  - *MD 0204 - Non-active soft tissue implants  * *MD 0300 - Devices for wound care	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 Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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

Name and address of the notified bodies	ID	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			

Name and address of the notified bodies	ID	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	medical devices - *MD 0101 - Non-active devices for anaesthesia,	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	No class III medical devices.
			conformity (production quality assurance)		
		, , , , , , , , , , , , , , , , , , , ,	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.
		transfusion and dialysis	EC declaration of conformity (production quality assurance)		
		, ,	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.
		devices	EC declaration of conformity (production quality assurance)		
		medical devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.
		3 1 111	EC declaration of conformity (production		

Name and address of the notified bodies	ID	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)	Annex II Annex V	No class III medical devices.
			EC declaration of conformity (production 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	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	quality assurance)  EC declaration of conformity (full quality assurance system)  EC declaration of	Annex II Annex V	No class III medical devices.
		*MD 0100 - General non-active, non-implantable	conformity (production quality assurance)  EC declaration of	Annex II	No class III medical devices.
		medical devices  - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	conformity (full quality	Annex V	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).

Name and address of the notified bodies	ID	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.

Name and address of the notified bodies	ID	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 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 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.

Name and address of the notified bodies	ID	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	Annex II Annex V	No class III medical devices.
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of	Annex II Annex V	No class III 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.

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		IVID 1401 Devices utilising formating radiation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		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	quality assurance)	Annex II Annex V	

Name and address of the notified bodies	ID	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	conformity (full quality	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	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 Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives \*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 Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*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

Name and address of the notified bodies	ID	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	ATTICK 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		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  Limited to non sterile class Im, IIa and IIb devices  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		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification		
		*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 lm, IIa and IIb devices
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification		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		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

Name and address of the notified bodies	ID	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
			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, Ila and Ilb devices
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Limited to non sterile class lm, Ila and Ilb devices
TUV Rheinland Italia SRL Via Mattei, 3 20010 - Pogliano Milanese (MI) Italy	1936	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	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	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 ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives medical devices conformity (full quality Annex V - \*MD 0103 - Non-active orthopaedic and rehabilitation assurance system) Annex VI EC declaration of devices conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC declaration of Annex II Excluding class III medical devices medical devices conformity (full quality Annex V assurance system) - \*MD 0104 - Non-active medical devices with Annex VI EC declaration of measuring function conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 0100 - General non-active, non-implantable EC declaration of Excluding class III medical devices Annex II medical devices conformity (full quality Annex V assurance system) - \*MD 0105 - Non-active ophthalmologic devices Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)

EC declaration of

conformity (full quality

Annex II

Annex V

\*MD 0100 - General non-active, non-implantable

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	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	

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence articles of the **bodies** or modules directives conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) EC type-examination \*MD 1100 - General active medical devices Annex III Excluding class III medical devices - \*MD 1109 - Active devices for patient positioning and EC verification Annex IV transport EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) Annex II \*MD 1100 - General active medical devices EC declaration of Excluding class III medical devices conformity (full quality - \*MD 1111 - Software Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality

assurance)

ι	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 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)	, uniox iv	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					

Name and address of the notified bodies	ID	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

Name and address of the notified bodies	ID	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	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified ID Responsible for the following products Responsible for the **Limitations (English only)** Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*MD 1302 - Monitoring devices of vital physiological EC verification Annex IV parameters EC declaration of Annex II conformity (full quality Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo Excluding class III medical devices EC declaration of Annex II conformity (full quality therapy Annex V assurance system) - \*MD 1401 - Devices utilising ionizing radiation Annex VI EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance) \*MD 1400 - Devices for radiation therapy and thermo EC verification Annex IV Excluding class III medical devices therapy EC declaration of Annex II conformity (full quality - \*MD 1402 - Devices utilising non-ionizing radiation Annex V assurance system) Annex VI EC declaration of conformity (production quality assurance)

EC declaration of

conformity (product quality

Name and address of the notified bodies	ID	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)	Annex II Annex V Annex VI	Excluding class III medical devices
			EC declaration of conformity (production quality assurance)	, umox vi	
			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)	Annex II Annex V Annex VI	Excluding class III medical devices
			EC declaration of conformity (production quality assurance)	, unica vi	
			EC declaration of conformity (product quality assurance)		
		*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	
			EC declaration of conformity (production quality assurance)		
			EC declaration of conformity (product quality assurance)		

Name and address of the notified bodies	ID	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			

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives absorbed \*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software Kiwa Belgelendirme Hizmetleri A.#. 1984 \*MD 1200 - Devices for imaging EC declaration of Annex II Tepeören Mevkii Ankara Asfalt# Maret Arkas# conformity (full quality - \*MD 1201 - Imaging devices utilising ionizing Annex V TOSB 9. Cadde No: 15 Tuzla Istanbul assurance system) radiation Turkey EC declaration of - \*MD 1202 - Imaging devices utilising non-ionizing conformity (production radiation quality assurance) \*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

	- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	 	
	distincting, clearing, finding		
	- *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		
7	*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		
9	*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	1	

- \*MD 1111 - Software

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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,

Name and address of the notified bodies	ID	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	2195	_	Full quality assurance system	Annex II Annex V	
#STANBUL Turkey			Production quality assurance		
		- *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			
		, · · ·	EC declaration of conformity (full quality	Annex II Annex V	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 0202 - Non-active orthopaedic implants	system	Annex V	
		- *MD 0203 - Non-active functional implants	Production quality		
		- *MD 0204 - Non-active soft tissue implants	assurance		
		*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			

Name and address of the notified bodies	ID	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	EC declaration of	Annex II	
		- *MD 1108 - Active rehabilitation devices and active prostheses	conformity (full quality assurance system)	Annex V	
		- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (production quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive			

Name and address of the notified bodies	ID	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	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	
		medical devices	Full quality assurance system Production quality	Annex II Annex V Annex VI	
		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			

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*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 Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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

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

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1104 - Active surgical devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1106 - Active dental devices	system	Annex V	
			Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	
		- *MD 1109 - Active devices for patient positioning and		Annex V	
		transport	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	
		- *MD 1111 - Software	conformity (full quality assurance system)	Annex V	
			EC declaration of	Annex VI	
			conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	
		- *MD 1107 - Active devices for disinfection and	conformity (full quality	Annex V	

Name and address of the notified bodies	ID	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)	Annex VI	
			EC declaration of		
			conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	
		- *MD 1102 - Respiratory devices, devices including	conformity (full quality	Annex V	
		hyperbaric chambers for oxygen therapy, inhalation	assurance system)	Annex VI	
		anaesthesia	EC declaration of		
			conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1100 - General active medical devices	EC declaration of	Annex II	without acitive prostheses
		- *MD 1108 - Active rehabilitation devices and active	conformity (full quality	Annex V	
		prostheses	assurance system)	Annex VI	
			EC declaration of		
			conformity (production		
			quality assurance)		
			EC declaration of		
			conformity (product quality		
			assurance)		
		*MD 1200 - Devices for imaging	Full quality assurance	Annex II	
		- *MD 1201 - Imaging devices utilising ionizing	system	Annex V	
		radiation	Production quality	Annex VI	

Name and address of the notified bodies	ID	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	Full quality assurance	Annex II	
		- *MD 1202 - Imaging devices utilising non-ionizing	system	Annex V	
		radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1300 - Monitoring devices	Full quality assurance	Annex II	
		- *MD 1301 - Monitoring devices of non-vital	system	Annex V	
		physiological parameters	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 1300 - Monitoring devices	Full quality assurance	Annex II	
		- *MD 1302 - Monitoring devices of vital physiological	system	Annex V	
		parameters	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices	system	Annex V	
		- *MD 0102 - Non-active devices for injection, infusion transfusion and dialysis	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable	Full quality assurance	Annex II	
		medical devices	system	Annex V	
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Production quality assurance	Annex VI	
			Product quality assurance		

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	Full quality assurance system	Annex II Annex V	
		- *MD 1402 - Devices utilising non-ionizing radiation	Production quality assurance	Annex VI	
			Product quality assurance		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	
			EC declaration of conformity (production quality assurance)	Allilex VI	
			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)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)	Annex VI	
			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)	Annex II	

Name and address of the notified bodies	ID	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)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	

Name and address of the notified bodies	ID	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		Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	a and a marity of fault and ality	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	conformity (full quality	Annex II Annex V	excluding dialysers

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)		
		*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	
			EC declaration of conformity (production 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)	Annex II Annex V	
			EC declaration of conformity (production quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality	Annex II Annex V	

Name and address of the notified bodies	ID	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)	Annex II Annex V	
			EC declaration of conformity (production 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 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	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives Turkev - \*MD 0303 - Other medical devices for wound care EC declaration of conformity (production \*MD 0100 - General non-active, non-implantable quality assurance) 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

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Name and address of the notified Responsible for the following products Responsible for the **Limitations (English only)** ID Annexes or following procedures /Horizontal technical competence **bodies** articles of the or modules directives - \*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

Name and address of the notified bodies	ID	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	

Name and address of the notified bodies	ID	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	assurance)		
		- *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			

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives - \*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 regarding Annex II, V, VI substances, according to Directive 2001/83/EC

\*MDS 7004 - Medical devices referencing the Directive

regarding Annex II, V, VI

Name and address of the notified bodies	ID	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,	quality assurance)	Annex II Annex V	

#### LIST OF BODIES NOTIFIED UNDER DIRECTIVE: 93/42/EEC Medical devices Responsible for the following products Responsible for the **Limitations (English only)** Name and address of the notified ID Annexes or following procedures **bodies** /Horizontal technical competence articles of the or modules directives (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 EC verification Annex IV - \*MD 0401 - Non-active dental equipment and EC declaration of Annex II conformity (full quality instruments Annex V assurance system) - \*MD 0402 - Dental materials EC declaration of conformity (production quality assurance) \*MD 0400 - Non-active dental devices and accessories EC declaration of Annex II conformity (full quality - \*MD 0403 - Dental implants Annex V assurance system) \*MD 1100 - General active medical devices EC declaration of - \*MD 1101 - Devices for extra-corporal circulation, conformity (production infusion and haemopheresis quality assurance) - \*MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia

- \*MD 1103 - Devices for stimulation or inhibition

Name and address of the notified bodies	ID	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			

Name and address of the notified bodies	ID	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			