applicable for ☐ MDR ☒ IVDR

Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/746 (IVDR)

Name of the national authority responsible for notified bodies (DA)	
Name of the applicant conformity assessment body (CAB) and, if applicable, notified body's identification number[1]	
Address of the CAB	
Date of application (not before 26 Nov 2017)	

I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

Please mark the selected types of products and conformity assessment activities with a cross (X) in the grey coloured columns below. The different lists of codes are in accordance with the Implementing Regulation on the list of codes[2]. Conformity assessment activities are identified by the corresponding reference to the Annex of the MDR.

The products and activities selected below will constitute the applied-for scope of application and therefore should be linked to the conformity assessment body's competence. Conditions, such as limitations must be included when applicable (e.g. when the competence cannot be justified for the whole code).

[1] In case of a new applicant, please insert « new »

[2] Commission Implementing Regulation (EU) 2017/XX of 24 November 2017 (expected) on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

1. Devices intended to be used for blood grouping

IVR CODE	Devices intended to be used to determine markers of the specific blood grouping systems to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	☐	☐	☐	☐	
IVR 0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	☐	☐	☐	☐	
IVR 0103	Devices intended to determine markers of the Kell system [Kel1 (K)]	☐	☐	☐	☐	
IVR 0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	☐	☐	☐	☐	
IVR 0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	☐	☐	☐	☐	
IVR CODE	**Other devices intended to be used for blood grouping**					
IVR 0106	Other devices intended to be used for blood grouping	☐	☐	☐	☐	

2. Devices intended to be used for tissue typing

IVR CODE	Devices intended to be used for tissue typing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0201	Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	☐	☐	☐	☐	
IVR 0202	Other devices intended to be used for tissue typing	☐	☐	☐	☐	

3. Devices intended to be used for markers of cancer and non-malignant tumours

IVR CODE	Devices intended to be used for markers of cancer and non-malignant tumours except devices for human genetic testing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0301	Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	☐	☐	☐	☐	
IVR 0302	Other devices intended to be used for markers of cancer and non-malignant tumours	☐	☐	☐	☐	

4. Devices intended to be used for for human genetic testing

IVR CODE	Devices intended to be used for human genetic testing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0401	Devices intended to be used in screening / confirmation of congenital / inherited disorders	☐	☐	☐	☐	
IVR 0402	Devices intended to be used to predict genetic disease/disorder risk and prognosis	☐	☐	☐	☐	
IVR 0403	Other devices intended to be used for human genetic testing	☐	☐	☐	☐	

5. Devices intended to be used to determine markers of infections / immune status

IVR CODE	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0501	Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	☐	☐	☐	☐	
IVR 0502	Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	☐	☐	☐	☐	

IVR CODE	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	☐	☐	☐	☐	
IVR 0504	Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	☐	☐	☐	☐	
IVR 0505	Devices intended to be used to grow / isolate / identify and handle infectious agents	☐	☐	☐	☐	
IVR 0506	Other devices intended to be used to determine markers of infections / immune status	☐	☐	☐	☐	

6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders / impairments (except human genetic testing), and therapeutic measures

IVR CODE	Devices intended to be used for a specific disease	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0601	Devices intended to be used for screening / confirmation of specific disorders / impairments	☐	☐	☐	☐	
IVR 0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	☐	☐	☐	☐	
IVR 0603	Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances	☐	☐	☐	☐	
IVR 0604	Other devices intended to be used for a specific disease	☐	☐	☐	☐	
IVR CODE	**Devices intended to be used to define or monitor physiological status and therapeutic measures**					
IVR 0605	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	☐	☐	☐	☐	
IVR 0606	Devices intended to be used for non-infectious disease staging	☐	☐	☐	☐	
IVR 0607	Devices intended to be used for detection of pregnancy or fertility testing	☐	☐	☐	☐	

IVR 0608	Devices intended to be used for screening, determination or monitoring of physiological markers	☐	☐	☐	☐	
IVR 0609	Other devices intended to be used to define or monitor physiological status and therapeutic measures	☐	☐	☐	☐	

7. Devices which are controls without a quantitative or qualitative assigned value

IVR CODE	**Controls without a quantitative or qualitative assigned value**	**Annexes**				**Conditions**
		IX(I)	**IX(II)**	**X**	**XI**	
IVR 0701	Devices which are controls without a quantitative assigned value	☐	☐	☐	☐	
IVR 0702	Devices which are controls without a qualitative assigned value	☐	☐	☐	☐	

8. Class A devices in sterile condition

IVR CODE	**Class A devices in sterile condition**	**Annexes**				**Conditions**
		IX(I)	**IX(II)**	**X**	**XI**	
IVR 0801	Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746	☐	☐	☐	☐	
IVR 0802	Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746	☐	☐	☐	☐	
IVR 0803	Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746	☐	☐	☐	☐	

II HORIZONTAL CODES

Please mark the selected horizontal areas and technologies in the grey coloured columns below. The different lists of codes are in accordance with the Implementing Regulation on the list of codes.

The areas and technologies selected will be part of the applied-for scope of application and therefore each of these areas should be linked to the conformity assessment body's competence. Conditions, such as limitations must be included when applicable (e.g. when the competence cannot be justified for the whole code).

1. In vitro diagnostic devices with specific characteristics

IVS CODE	In vitro diagnostic devices with specific characteristics	Select	Conditions
IVS 1001	Devices intended to be used for near-patient testing	☐	
IVS 1002	Devices intended to be used for self-testing	☐	
IVS 1003	Devices intended to be used as companion diagnostics	☐	
IVS 1004	Devices manufactured utilising tissues or cells of human origin, or their derivatives	☐	
IVS 1005	Devices in sterile condition	☐	Please indicate which of the following processes are covered Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) If designation is sought for other processes, these need to be specified
IVS 1006	Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	☐	
IVS 1007	Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746)	☐	
IVS 1008	Instruments, equipment, systems or apparatus	☐	
IVS 1009	Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	☐	

IVS CODE	In vitro diagnostic devices with specific characteristics	Select	Conditions
IVS 1010	Devices incorporating software / utilising software / controlled by software	☐	

2. In vitro diagnostic devices for which specific technologies are used

IVT CODE	In vitro diagnostic devices for which specific technologies are used	Select	Conditions
IVT 2001	In vitro diagnostic devices manufactured using metal processing	☐	
IVT 2002	In vitro diagnostic devices manufactured using plastic processing	☐	
IVT 2003	In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	☐	
IVT 2004	In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	☐	
IVT 2005	In vitro diagnostic devices manufactured using biotechnology	☐	
IVT 2006	In vitro diagnostic devices manufactured using chemical processing	☐	
IVT 2007	In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	☐	
IVT 2008	In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	☐	
IVT 2009	In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	☐	
IVT 2010	In vitro diagnostic devices manufactured using electronic components including communication devices	☐	
IVT 2011	In vitro diagnostic devices which require packaging, including labelling	☐	

3. In vitro diagnostic devices which require specific knowledge in examination procedures for the purpose of product verification

IVP CODE	In vitro diagnostic devices which require specific knowledge in examination procedures	Select	Conditions
IVP 3001	In vitro diagnostic devices which require knowledge regarding agglutination tests	☐	
IVP 3002	In vitro diagnostic devices which require knowledge regarding biochemistry	☐	
IVP 3003	In vitro diagnostic devices which require knowledge regarding chromatography	☐	
IVP 3004	In vitro diagnostic devices which require knowledge regarding chromosomal analysis	☐	
IVP 3005	In vitro diagnostic devices which require knowledge regarding coagulometry	☐	
IVP 3006	In vitro diagnostic devices which require knowledge regarding flow cytometry	☐	
IVP 3007	In vitro diagnostic devices which require knowledge regarding immunoassays	☐	
IVP 3008	In vitro diagnostic devices which require knowledge regarding lysis based testing	☐	
IVP 3009	In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	☐	
IVP 3010	In vitro diagnostic devices which require knowledge regarding microscopy	☐	
IVP 3011	In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	☐	
IVP 3012	In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	☐	
IVP 3013	In vitro diagnostic devices which require knowledge regarding spectroscopy	☐	
IVP 3014	In vitro diagnostic devices which require knowledge regarding tests of cell function	☐	

4. In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification

IVP CODE	In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification	Select	Conditions
IVD 4001	In vitro diagnostic devices which require knowledge regarding bacteriology	☐	
IVD 4002	In vitro diagnostic devices which require knowledge regarding clinical chemistry / biochemistry	☐	
IVD 4003	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	☐	
IVD 4004	In vitro diagnostic devices which require knowledge regarding genetics	☐	
IVD 4005	In vitro diagnostic devices which require knowledge regarding haematology / haemostasis, including coagulation disorders	☐	
IVD 4006	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	☐	
IVD 4007	In vitro diagnostic devices which require knowledge regarding immunohistochemistry / histology	☐	
IVD 4008	In vitro diagnostic devices which require knowledge regarding immunology	☐	
IVD 4009	In vitro diagnostic devices which require knowledge regarding molecular biology / diagnostics	☐	
IVD 4010	In vitro diagnostic devices which require knowledge regarding mycology	☐	
IVD 4011	In vitro diagnostic devices which require knowledge regarding parasitology	☐	
IVD 4012	In vitro diagnostic devices which require knowledge regarding virology	☐	