applicable for ☐ MDR and ☒ IVDR

WD 2017-3

Draft list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies under the Regulation (EU) 2017/746 (IVDR)

This draft list of codes has been created in the context of preparations of the future implementing act under Article 38(13) IVDR. The document has not been adopted or endorsed by the European Commission, and any views expressed reflect the preliminary discussions of the Commission services and Member States' authorities, and they may not be regarded as stating an official position of the Commission.

The document is intended for information about the preparatory works on the future implementing legislation and it is without prejudice to the final text of such implementing legislation.

Any draft implementing legislation will be made available for public feedback in due time, through the feedback mechanism at the following website:

https://ec.europa.eu/info/law/better-regulation/have-your-say_en

I) CODES ACCORDING TO THE DEVICE TYPE

(1) Devices intended to be used for blood grouping

IVR CODE	**Devices intended to be used for blood grouping to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration**
IVR 0101	ABO system [A (ABO1), B (ABO2), AB (ABO3)]
IVR 0102	Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
IVR 0103	Kell system [Kel1 (K)]
IVR 0104	Kidd system [JK1 (Jka), JK2 (Jkb)]
IVR 0105	Duffy system [FY1 (Fya), FY2 (Fyb)]
IVR 0106	Other devices for blood grouping according to Annex VIII rule 2[1]
IVR CODE	**Other devices intended to be used for blood grouping**
IVR 0107	Devices intended to be used for blood grouping (except Annex VIII rule 2)

[1] Each time when Annex VIII is mentioned, a reference is made to Annex VIII of Regulation (EU) 2017/746.

(2) Devices intended to be used for tissue typing

IVR CODE	**Devices intended to be used for tissue typing**
IVR 0201	Devices intended to be used for tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration (HLA A, B, DR)
IVR 0202	Other devices intended to be used for tissue typing according to Annex VIII rule 2
IVR 0203	Other devices intended to be used for tissue typing (except Annex VIII rule 2)

(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**
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 human genetic testing

IVR CODE	**Devices intended to be used for human genetic testing**
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 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**
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 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, and disorders / impairments (except human genetic testing)

IVR CODE	**Devices intended to be used for a specific disease**
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**
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**
IVR 0801	Products for general laboratory use according to Annex VIII rule 5 a)
IVR 0802	Instruments intended specifically to be used for in vitro diagnostic procedures according to Annex VIII rule 5 b)
IVR 0803	Specimen receptacles according to Annex VIII rule 5 c)

II) HORIZONTAL CODES

(1) Specifics of in vitro diagnostic medical devices

IVS CODE	**IVDR specifics**
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 utilizing material of human origin
IVS 1005	Devices in sterile condition
IVS 1006	Calibrators (Annex VIII 1.5)
IVS 1007	Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (Annex VIII 1.6)
IVS 1008	Instruments, equipment, systems or apparatus
IVS 1009	Software independent of any other device including software apps, software for data analysis, and for defining or monitoring therapeutic measures
IVS 1010	Devices incorporating software / utilising software / controlled by software

(2) Technologies for in vitro diagnostic medical devices – auditing

IVT CODE	**IVDR manufacturing technologies**
IVT 2001	Metal processing
IVT 2002	Plastic processing
IVT 2003	Non-metal mineral processing including glass, ceramics
IVT 2004	Non-metal non-mineral processing including textiles, rubber, leather, paper
IVT 2005	Biotechnology
IVT 2006	Chemical processing
IVT 2007	Production of pharmaceuticals
IVT 2008	Clean room production
IVT 2009	Processing of materials of human, animal or microbial origin
IVT 2010	Manufacture or processing of electronic components including communication devices
IVT 2011	Packaging, including labelling

(3) Types of examination procedures – product verification

IVDP CODE	**IVDR types of examination procedures**
IVP 3001	Agglutination tests
IVP 3002	Biochemistry
IVP 3003	Chromatography
IVP 3004	Chromosomal analysis
IVP 3005	Coagulometry
IVP 3006	Flow cytometry
IVP 3007	Immunoassays
IVP 3008	Lysis based testing
IVP 3009	Measurement of radioactivity
IVP 3010	Microscopy
IVP 3011	Molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
IVP 3012	Physical chemistry including electrochemistry
IVP 3013	Spectroscopy
IVP 3014	Tests of cell function

(4) Laboratory and clinical disciplines - product verification

IVDD CODE	**IVDR laboratory and clinical disciplines**
IVD 4100	Bacteriology
IVD 4101	- Multi-drug-resistant *mycobacterium* species (tuberculosis)
IVD 4102	- *Vibrio cholerae* (cholera)
IVD 4103	- Multi-resistant *Staphylococcus aureus* (and / or tests for resistance genes)
IVD 4104	- *Treponema pallidum* (syphilis)
IVD 4200	Clinical chemistry / biochemistry
IVD 4300	Detection of transmissible agents (without organisms or viruses)
IVD 4301	- Prion (Creutzfeldt-Jakob disease (CJD) and variant CJD (vCJD))
IVD 4400	Genetics

IVD 4500	Haematology / haemostasis, including coagulation disorders‘
IVD 4600	Histocompatability and immunogenetics
IVD 4700	Immunohistochemistry / histology
IVD 4800	Immunology
IVD 4900	Molecular biology / diagnostics
IVD 5000	Mycology
IVD 5100	Parasitology
IVD 5101	- *Plasmodium* species (malaria)
IVD 5102	- *Toxoplasma gondii* (toxoplasmosis)
IVD 5103	- *Trypanosoma cruzi* (Chagas disease)
IVD 5200	Virology
IVD 5201	- Cytomegalovirus (CMV IgG)
IVD 5202	- Epstein-Barr virus (EBV)
IVD 5203	- Hepatitis B, C, D, E
IVD 5204	- Highly virulent pandemic influenza
IVD 5205	- HIV 1 & 2 (HIV / AIDS)
IVD 5206	- Human T-lymphotropic virus (HTLV)
IVD 5207	- SARS - coronavirus (SARS)
IVD 5208	- Lassa fever virus, Ebola virus, Marburg virus (viral haemorrhagic fevers)
IVD 5209	- West Nile virus (West Nile fever)
IVD 5210	- Zika virus (Zika fever)