COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185

of 23 November 2017

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([1]), and in particular Articles 39(10) and 42(13) thereof,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ([2]), and in particular Articles 35(10) and 38(13) thereof,

Whereas:

(1) Conformity assessment of medical devices under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 may carry out such assessment and only for the activities related to the types of devices concerned. In order to enable specifying the scope of the designation of conformity assessment bodies notified under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 it is necessary to draw up list of codes and corresponding types of devices.

(2) The lists of codes and corresponding types of devices should take into account various device types which can be characterised by design and intended purpose, manufacturing processes and technologies used, such as sterilisation and the use of nanomaterials. The lists of codes should provide for a multi-dimensional typology of devices which ensures that conformity assessment bodies designated as notified bodies are fully competent for the devices they are required to assess.

(3) In accordance with Article 42(3) of Regulation (EU) 2017/745 and Article 38(3) of Regulation (EU) 2017/746, when notifying the Commission and the other Member States of the conformity assessment bodies they have designated Member States are to clearly specify, using the codes, the scope of the designation indicating the conformity assessment activities and the types of devices which the notified body is authorised to assess. In order to facilitate such notification and the assessment of the application for designation referred to in Article 38 of Regulation (EU) 2017/745 and Article 34 of Regulation (EU) 2017/746, conformity assessment bodies should use the lists of codes and corresponding types of devices set out in this Regulation when applying for designation.

(4) Experience shows that conformity assessment bodies applying for designation in the field of *in vitro* diagnostic medical devices also apply for designation for medical devices under Regulation (EU) 2017/745. It is therefore appropriate, for reasons of user-friendliness, to include the lists of codes for Regulation (EU) 2017/745 and for Regulation (EU) 2017/746 in one Implementing Regulation.

(5) As of 26 November 2017, conformity assessment bodies may submit an application for designation as a notified body under Regulation (EU) 2017/745 and Regulation (EU) 2017/746. In order to enable the conformity assessment bodies to use the codes laid down in this Regulation in the application for designation, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 117, 5.5.2017, p. 1.
([2]) OJ L 117, 5.5.2017, p. 176.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

List of codes

1. 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 is set out in Annex I to this Regulation.

2. 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 *in vitro* diagnostic medical devices under Regulation (EU) 2017/746 is set out in Annex II to this Regulation.

Article 2

Application for designation

Conformity assessment bodies shall use the lists of codes and corresponding types of devices set out in Annexes I and II to this Regulation when specifying the types of devices in the application for designation referred to in Article 38 of Regulation (EU) 2017/745 and Article 34 of Regulation (EU) 2017/746.

Article 3

Entry into force

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 November 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

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

I. **CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**

A. **Active devices**

1. *Active implantable devices*

MDA CODE	Active implantable devices
MDA 0101	Active implantable devices for stimulation/inhibition/monitoring
MDA 0102	Active implantable devices delivering drugs or other substances
MDA 0103	Active implantable devices supporting or replacing organ functions
MDA 0104	Active implantable devices utilising radiation and other active implantable devices

2. *Active non-implantable devices for imaging, monitoring and/or diagnosis*

MDA CODE	Active non-implantable devices for imaging, monitoring and/or diagnosis
MDA 0201	Active non-implantable imaging devices utilising ionizing radiation
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters
MDA 0204	Other active non-implantable devices for monitoring and/or diagnosis

3. *Active non-implantable therapeutic devices and general active non-implantable devices*

MDA CODE	Active non-implantable therapeutic devices and general active non-implantable devices
MDA 0301	Active non-implantable devices utilising ionizing radiation
MDA 0302	Active non-implantable devices utilising non-ionizing radiation
MDA 0303	Active non-implantable devices utilising hyperthermia/hypothermia
MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)
MDA 0305	Active non-implantable devices for stimulation or inhibition
MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis
MDA 0307	Active non-implantable respiratory devices
MDA 0308	Active non-implantable devices for wound and skin care
MDA 0309	Active non-implantable ophthalmologic devices
MDA 0310	Active non-implantable devices for ear, nose and throat

MDA CODE	Active non-implantable therapeutic devices and general active non-implantable devices
MDA 0311	Active non-implantable dental devices
MDA 0312	Other active non-implantable surgical devices
MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
MDA 0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs including *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MDA 0315	Software
MDA 0316	Medical gas supply systems and parts thereof
MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation
MDA 0318	Other active non-implantable devices

B. **Non-active devices**

1. *Non-active implants and long term surgically invasive devices*

MDN CODE	Non-active implants and long term surgically invasive devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1103	Non-active dental implants and dental materials
MDN 1104	Non-active soft tissue and other implants

2. *Non-active non-implantable devices*

MDN CODE	Non-active non-implantable devices
MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
MDN 1204	Non-active non-implantable devices for wound and skin care
MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices
MDN 1206	Non-active non-implantable ophthalmologic devices
MDN 1207	Non-active non-implantable diagnostic devices
MDN 1208	Non-active non-implantable instruments

MDN CODE	Non-active non-implantable devices
MDN 1209	Non-active non-implantable dental materials
MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing
MDN 1212	Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body *via* a body orifice or the dermal route
MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices

II. **HORIZONTAL CODES**

1. *Devices with specific characteristics*

MDS CODE	Devices with specific characteristics
MDS 1001	Devices incorporating medicinal substances
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives
MDS 1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives
MDS 1004	Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council [1]
MDS 1005	Devices in sterile condition
MDS 1006	Reusable surgical instruments
MDS 1007	Devices incorporating or consisting of nanomaterial
MDS 1008	Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body
MDS 1009	Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices
MDS 1010	Devices with a measuring function
MDS 1011	Devices in systems or procedure packs
MDS 1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
MDS 1013	Class III custom-made implantable devices
MDS 1014	Devices incorporating as an integral part an *in vitro* diagnostic device

[1] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006, p. 24).

2. *Devices for which specific technologies or processes are used*

MDT CODE	Devices for which specific technologies or processes are used
MDT 2001	Devices manufactured using metal processing
MDT 2002	Devices manufactured using plastic processing
MDT 2003	Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)
MDT 2004	Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)
MDT 2005	Devices manufactured using biotechnology
MDT 2006	Devices manufactured using chemical processing
MDT 2007	Devices which require knowledge regarding the production of pharmaceuticals
MDT 2008	Devices manufactured in clean rooms and associated controlled environments
MDT 2009	Devices manufactured using processing of materials of human, animal, or microbial origin
MDT 2010	Devices manufactured using electronic components including communication devices
MDT 2011	Devices which require packaging, including labelling
MDT 2012	Devices which require installation, refurbishment
MDT 2013	Devices which have undergone reprocessing

ANNEX II

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 *in vitro* diagnostic medical devices under Regulation (EU) 2017/746

I. **CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**

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

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
	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	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**

1. *In vitro diagnostic devices with specific characteristics*

IVS CODE	In vitro diagnostic devices with specific characteristics
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
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 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
IVT 2001	In vitro diagnostic devices manufactured using metal processing
IVT 2002	In vitro diagnostic devices manufactured using plastic processing

IVT CODE	In vitro diagnostic devices for which specific technologies are used
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
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 CODE	In vitro diagnostic devices which require specific knowledge in examination procedures
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*

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