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)

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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2185. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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*.

(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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2185. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2185. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2185. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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 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