MDCG 2021-18

Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)

July 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/745 (MDR)[1]

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[2]	
Address of the CAB	
Date of application	

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[3]. Conformity assessment activities are identified by the corresponding reference to the Annex of the MDR.

[1] This document was endorsed by MDCG and published as NBOG F 2017-3 in its first version in February 2018. Based on experience gained in the context of the joint assessment process, the document has been updated and its revision published as MDCG document.
[2] In case of a new applicant, please insert « new »
[3] 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

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).

A ACTIVE DEVICES

MDA CODE	Active implantable devices	Annexes					Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
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	☐	☐	☐	☐	☐	

MDA CODE	Active non-implantable devices for imaging, monitoring and / or diagnosis	Annexes					Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
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	☐	☐	☐	☐	☐	

MDA CODE	Active non-implantable therapeutic devices and general active non-implantable devices	Annexes					Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
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 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

MDN CODE	**Non-active implants and long term surgically invasive devices**	**Annexes**					**Conditions**
		IX(I)	**IX(II)**	**X**	**XI(A)**	**XI(B)**	
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	☐	☐	☐	☐	☐	

MDN CODE	Non-active non-implantable devices	Annexes					Conditions
		IX(I)	IX(II)	X	XI(A)	XI(B)	
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 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 pre-servation 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

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).

MDS CODE	Devices with specific characteristics	Select	Conditions
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[4]	☐	
MDS 1005	Devices in sterile condition	*Please indicate which of the following processes are covered:*	
		☐	aseptic processing
		☐	ethylene oxide gas sterilisation (EOG)
		☐	low temperature steam and formaldehyde sterilisation
		☐	moist heat sterilisation
		☐	radiation sterilisation (gamma, x-ray, electron beam)
		☐	sterilisation with hydrogen peroxide

[4] 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).

		☐ ☐ ☐	sterilisation with liquid chemical sterilising agents thermic sterilisation with dry heat Other sterilisation processes, please specify: *If designation is sought also for other processes, these need to be specified.*
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	☐	

MDT CODE	Devices for which specific technologies or processes are used	Select	Conditions
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	☐	