

MDCG 2021-17

Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR)

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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applicable for MDR IVDR

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 number²	
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 codes³. 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

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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0102	Active implantable devices delivering drugs or other substances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0103	Active implantable devices supporting or replacing organ functions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0104	Active implantable devices utilising radiation and other active implantable devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0204	Other active non-implantable devices for monitoring and / or diagnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0302	Active non-implantable devices utilising non-ionizing radiation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0303	Active non-implantable devices utilising hyperthermia / hypothermia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0305	Active non-implantable devices for stimulation or inhibition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0307	Active non-implantable respiratory devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0308	Active non-implantable devices for wound and skin care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0309	Active non-implantable ophthalmologic devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0310	Active non-implantable devices for ear, nose and throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0311	Active non-implantable dental devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0312	Other active non-implantable surgical devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0315	Software	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0316	Medical gas supply systems and parts thereof	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDA 0318	Other active non-implantable devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1102	Non-active osteo- and orthopaedic implants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1103	Non-active dental implants and dental materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1104	Non-active soft tissue and other implants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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

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MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1204	Non-active non-implantable devices for wound and skin care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1206	Non-active non-implantable ophthalmologic devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1207	Non-active non-implantable diagnostic devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1208	Non-active non-implantable instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1209	Non-active non-implantable dental materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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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	<input type="checkbox"/>	
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives	<input type="checkbox"/>	
MDS 1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives	<input type="checkbox"/>	
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	<input type="checkbox"/>	
MDS 1005	Devices in sterile condition	<i>Please indicate which of the following processes are covered:</i> <ul style="list-style-type: none"> <input type="checkbox"/> aseptic processing <input type="checkbox"/> ethylene oxide gas sterilisation (EOG) <input type="checkbox"/> low temperature steam and formaldehyde sterilisation <input type="checkbox"/> moist heat sterilisation 	

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).

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		<input type="checkbox"/> radiation sterilisation (gamma, x-ray, electron beam) <input type="checkbox"/> sterilisation with hydrogen peroxide <input type="checkbox"/> sterilisation with liquid chemical sterilising agents <input type="checkbox"/> thermic sterilisation with dry heat <input type="checkbox"/> Other sterilisation processes, please specify: <i>If designation is sought also for other processes, these need to be specified.</i>
MDS 1006	Reusable surgical instruments	<input type="checkbox"/>
MDS 1007	Devices incorporating or consisting of nanomaterial	<input type="checkbox"/>
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	<input type="checkbox"/>
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	<input type="checkbox"/>
MDS 1010	Devices with a measuring function	<input type="checkbox"/>
MDS 1011	Devices in systems or procedure packs	<input type="checkbox"/>
MDS 1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	<input type="checkbox"/>
MDS 1013	Class III custom-made implantable devices	<input type="checkbox"/>
MDS 1014	Devices incorporating as an integral part an <i>in vitro</i> diagnostic device	<input type="checkbox"/>

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