



applicable for MDR and IVDR

WD 2017-2

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) 2017/745 (MDR)

This draft list of codes has been created in the context of preparations of the future implementing act under Article 42(13) MDR. 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](https://ec.europa.eu/info/law/better-regulation/have-your-say_en) at the following website:

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

I) CODES ACCORDING TO THE DEVICE TYPE

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 substituting 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 haemopheresis
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 <i>in vitro</i> fertilisation (IVF) and assisted reproductive technologies (ART)
MDA 0315	Standalone 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 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 <i>in vitro</i> fertilisation (IVF) and assisted reproductive technologies (ART)
MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body <i>via</i> 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) Specifics of medical devices

MDS CODE	MDR specifics
MDS 1001	Devices incorporating medicinal substances
MDS 1002	Devices manufactured utilising tissues or cells of animal origin, or their derivatives
MDS 1003	Devices manufactured utilising tissues or cells of human 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 ¹
MDS 1005	Devices in sterile condition
MDS 1006	Reusable surgical instruments
MDS 1007	Devices incorporating or consisting of nanomaterial
MDS 1008	Devices utilising biological 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

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).

MDS 1012	Products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745
MDS 1013	Class III custom-made implantable devices
MDS 1014	Devices incorporating as an integral part an <i>in vitro</i> diagnostic medical device

(2) Technologies for medical devices – auditing

MDT CODE	MDR manufacturing technologies
MDT 2001	Metal processing
MDT 2002	Plastic processing
MDT 2003	Non-metal mineral processing including glass, ceramics
MDT 2004	Non-metal non-mineral processing including textiles, rubber, leather, paper
MDT 2005	Biotechnology
MDT 2006	Chemical processing
MDT 2007	Production of pharmaceuticals
MDT 2008	Clean room production
MDT 2009	Processing of materials of human or animal origin
MDT 2010	Manufacture or processing of electronic components including communication devices
MDT 2011	Packaging, including labelling
MDT 2012	Installation, refurbishment
MDT 2013	Reprocessing of medical devices