

Okružní 31, 638 00 Brno Czech Republic

Scope of the application on the designation of a notified body under the MDR (list of MDR codes)

A. ACTIVE DEVICES

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

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 0305 Active non-implantable devices for stimulation or inhibition
- MDA 0307 Active non-implantable respiratory devices
- MDA 0312 Other active non-implantable surgical devices
- 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

- MDN 1102 Non-active osteo- and orthopaedic implants
- MDN 1103 Non-active dental implants and dental materials

Non-active non-implantable devices

- MDN 1205 Non-active non-implantable orthopaedic and rehabilitation 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 1211 Non-active non-implantable devices used for disinfecting, cleaning and rinsing

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MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices

C. HORIZONTAL CODES

MDS CODE Devices with specific characteristics

- 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
- MDS 1005 Devices in sterile condition
- MDS 1006 Reusable surgical instruments
- MDS 1007 Devices incorporating or consisting of nanomaterial
- 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

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 2008 Devices manufactured in clean rooms and associated controlled environments
- 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

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