

Notification of a Body in the framework of a technical harmonization directive

From: Zentralstelle der Länder für
Gesundheitsschutz bei Arzneimitteln
und Medizinprodukten (ZLG)
Heinrich-Böll-Ring 10
53119 Bonn
Germany

To: European Commission
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference:

Legislation: Regulation (EU) 2017/745 on medical devices

Body name, address, telephone, fax, email, website :

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany
+49 201 825-0
+49 201 825-691055
tncert-accreditation@tuev-nord.de
www.tuev-nord.de/en/services/auditing-and-certification/

Body info:

NB 0044

Tasks performed by the Body:

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Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -2. Active non-implantable devices for imaging, monitoring and/or diagnosis -MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -2. Active non-implantable devices for imaging, monitoring and/or diagnosis -MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -2. Active non-implantable devices for imaging, monitoring and/or diagnosis -MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -2. Active non-implantable devices for imaging, monitoring and/or diagnosis -MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -1. Non-active implants and long term surgically invasive devices -MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -1. Non-active implants and long term surgically invasive devices -MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -1. Non-active implants and long term surgically invasive devices -MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -1. Non-active implants and long term surgically invasive devices -MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -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	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

Horizontal technical competences	Limitations
MDS 1001 Devices incorporating medicinal substances:	without medicinal products derived from human blood or human plasma
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 (1):	
MDS 1005 Devices in sterile condition:	including: 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; additional: Sterilisationsverfahren mit Plasma
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:	

Horizontal technical competences	Limitations
MDS 1011 Devices in systems or procedure packs:	
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device:	
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 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:	