

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 Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
Phone : +49 (0) 9116555225
Fax : +49 (0) 9116555226
Email : service@de.tuv.com
Website : www.tuv.com/safety

Body :

NB 0197

Tasks performed by the Body :

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Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
- A. Active devices			
- 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	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)	limited to stimulation devices excluding brain stimulators and pacemakers
- 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)	
- 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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 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)	
- 3. Active non-implantable therapeutic devices and	Conformity assessment based	Annex X	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding brain stimulation 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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding hyperbaric chamber

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	documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - 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) 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	
<ul style="list-style-type: none"> - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices 	<ul style="list-style-type: none"> Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based 	<ul style="list-style-type: none"> Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B) 	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	on product conformity verification		
- B. Non-active devices			
<ul style="list-style-type: none"> - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	excluding heart valves introduced into the body by open heart surgeries
<ul style="list-style-type: none"> - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	excluding joint implants
<ul style="list-style-type: none"> - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	
<ul style="list-style-type: none"> - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system 	<ul style="list-style-type: none"> Annex IX(I) Annex IX(II) Annex XI(A) 	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
- 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)	
- 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)	
- 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)	
- 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)	
- 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)	
- 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)	
- 2. Non-active non-implantable devices - 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)	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)	
- 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)	
- 2. Non-active non-implantable devices	Conformity assessment based on a quality management	Annex IX(I)	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
- MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	

Horizontal technical competence	Conditions
MDS 1001 Devices incorporating medicinal substances	
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 (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 sterilisation with liquid chemical sterilising agents thermic sterilisation with dry heat
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 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	excluding "under processing of materials of human 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	