

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

From : National Institute of Pharmacy
and Nutrition (OGYÉI)
Zrínyi u. 3.
H-1051 Budapest
Hungary

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 :

CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft.
Erd# u.101.
Budakeszi
Hungary
Phone : 00-36-23-880-830
Fax : 00-36-23-880-831
Email : info@cecertiso.hu
Website : www.cecertiso.hu

Body :

NB 2409

Tasks performed by the Body :

Last approval date : 20/03/2020

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			
<ul style="list-style-type: none"> - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation 	<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. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters 	<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. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis 	<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 0302 Active non-implantable devices utilising non-ionizing radiation 	<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 0305 Active non-implantable devices for stimulation or inhibition 	<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 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis 	<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 0307 Active non-implantable respiratory devices 	<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 0308 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) 	

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 0310 Active non-implantable devices for ear, nose and throat 	<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 0311 Active non-implantable dental devices 	<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 0312 Other active non-implantable surgical devices 	<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 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 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 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 0317 Active non-implantable devices for cleaning, disinfection and sterilisation 	<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 0318 Other active non-implantable devices 	<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"> - 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) 	
<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 	<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 product quality assurance		
<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 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 1207 Non-active non-implantable diagnostic devices 	<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 1208 Non-active non-implantable instruments 	<ul style="list-style-type: none"> Conformity assessment based on a quality management system Conformity assessment based on assessment of technical 	<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
	documentation Conformity assessment based on product quality assurance		
- 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 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 - 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 competence	Conditions
MDS 1001 Devices incorporating medicinal substances	excluding medicinal substances derived from human blood or human plasma
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 liquid chemical sterilising agents, sterilisation with hydrogen peroxide, sterilisation with dry heat
MDS 1006 Reusable surgical instruments	
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	

Horizontal technical competence	Conditions
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 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 human origin
MDT 2010 Devices manufactured using electronic components including communication devices	
MDT 2011 Devices which require packaging, including labelling	