

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

From: Federal Ministry of Social Affairs,
Health, Care and Consumer
Protection
Radetzkystrasse 2

1030 Vienna
Austria

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

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Body info:

NB 2962

Tasks performed by the Body:

Last approval date: 2024-05-14

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 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)	Excluding: audiometers; ocular tonometer; retinal cameras
-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)	Excluding: lasers for pain treatment; patient photo therapy; robotic solution for the non-invasive echotherapy treatment of varicose veins; surgical laser for refractive surgery of the eye
-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)	Excluding: electrical acupuncture.

Product	Procedures	Articles /Annexes	Conditions
-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)	Excluding: blood pumps for heart-lung machines
-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)	Excluding: hyperbaric chambers
-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)	Excluding: pressure regulators for spraying surgical sealants/haemostats
-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)	Excluding: radiotherapy planning system
-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)	

Product	Procedures	Articles /Annexes	Conditions
-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)	Excluding: artificial spinal disc; prosthetic joint replacements (i.e. knee, hip implants); hyaluronic acid implant for intraarticular use; ligament reconstruction products (synthetic).
-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)	Limited to hernia meshes, urethral stent implants, sutures, collagen soft implants, adhesion (scarring) prevention implants; surgical hemostats and sealants/collagen-based hemostats
-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)	
-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)	Excluding: dialysis filters, dialysis solutions

Product	Procedures	Articles /Annexes	Conditions
-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)	Excluding: embolectomy catheter
-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)	Excluding: dental instruments
-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)	Limited to solutions and wipes for disinfecting medical devices

Horizontal technical competences	Limitations
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:	aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
MDS 1006 Reusable surgical instruments:	
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 1014 Devices incorporating as an integral part an in vitro diagnostic device:	

Horizontal technical competences	Limitations
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 2006 Devices manufactured using chemical processing:	
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:	
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:	

在技术协调指令框架内关于一个机构的通知

发件方：

联邦社会事务、卫生、护理与消费者保护部
拉德茨基大街2号

1030 维也纳
奥地利

致：

欧盟委员会增长总司
B-1049 布鲁塞尔

其他成员国

参考：

立法依据：《医疗器械条例》(EU) 2017/745

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主体信息：

NB 2962

机构执行的任务：

最后批准日期：

2024-05-14

产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 -A. 主动装置 -2. 用于成像、监测和/或诊断的非植入式主动设备 -MDA 0203 用于监测生命体征参数的非植入式主动设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	
-I. 反映器械设计和预期用途的代码 -A. 主动设备 -2. 用于成像、监测和/或诊断的非植入式主动设备 -MDA 0204 其他用于监测和/或诊断的非植入式主动设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	不包括：听力计；眼压计；视网膜相机
-I. 反映设备设计与预期用途的代码 -A. 主动式设备 -3. 主动式非植入治疗设备及通用主动式非植入设备 -MDA 0302 利用非电离辐射的非植入式主动设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	不包括：用于疼痛治疗的激光；患者光疗；用于静脉曲张非侵入性超声治疗的机器人解决方案；用于屈光手术的眼科手术激光 -I. 代码反映器械的设计和预期用途
-I. 反映器械设计和预期用途的代码 -A. 主动设备 -3. 主动式非植入治疗设备及通用主动式非植入设备 -MDA 0305 用于刺激或抑制的非植入式主动装置	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	不包括：电针疗法。

产品	程序	条文/附件	条件
-I. 反映器械设计与预期用途的代码 -A. 主动装置 -3. 主动式非植入治疗设备及通用主动式非植入设备 -MDA 0306 用于体外循环、物质给药或清除以及血液分离的非植入式活动装置	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	除外：心肺机用血液泵
-I. 反映器械设计与预期用途的代码 -A. 主动器械 -3. 主动式非植入治疗器械及通用主动式非植入器械 -MDA 0307 能动非植入式呼吸设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件 IX(I) 附件 IX(II) 附件 XI(A)	除外：高压氧舱
-I. 反映器械设计和预期用途的代码 -A. 主动设备 -3. 主动式非植入治疗器械及通用主动式非植入器械 -MDA 0312 其他非植入式手术用能动器械	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件 IX(I) 附件 IX(II) 附件 XI(A)	除外：用于喷涂外科密封剂/止血剂的压力调节器
-I. 反映器械设计与预期用途的代码 -A. 主动装置 -3. 主动非植入治疗器械及通用主动非植入器械 -MDA 0315 软件	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件 IX(I) 附件 IX(II) 附件 XI(A)	除外：放射治疗规划系统
-I. 反映器械设计和预期用途的代码 -A. 主动设备 -3. 主动式非植入治疗器械及通用主动式非植入器械 -MDA 0318 其他有源非植入式器械	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	

产品	程序	条文/附件	条件
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -1. 非活性植入物及长期外科侵入性器械 -MDN 1101 非活性心血管、血管及神经血管植入物	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -1. 非活性植入物及长期外科侵入性器械 -MDN 1102 非能动骨科及矫形植入物	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	不包括：人工椎间盘；假体关节置换（即膝关节、髋关节植入物）；关节内用透明质酸植入物；韧带重建产品（合成）。
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -1. 非活性植入物及长期外科侵入性器械 -MDN 1104 非能动软组织及其他植入物	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件九(I) 附件九(II) 附件十一(A)	仅限于疝气补片、尿道支架植入物、缝合线、胶原蛋白软植入物、粘连（瘢痕）预防植入物；外科止血剂和密封剂/胶原蛋白-基止血剂
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -2. 非活性非植入式器械 -MDN 1201 用于麻醉、急救和重症监护的非植入式非能动设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -2. 非主动非植入式器械 -MDN 1202 用于物质给药、输送和清除的非植入式非能动器械，包括透析器械	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	不包括：透析滤器、透析液

产品	程序	条款/附件	条件
-I. 反映设备设计与预期用途的代码 -B. 非主动式设备 -2. 非植入式非主动设备 -MDN 1203 非能动非植入式导引导管、球囊导管、导丝、导管套管、滤器及相关器械	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	除外：栓塞切除导管
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -2. 非能动非植入式器械 -MDN 1208 非能动非植入器械	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	除外：牙科器械
-I. 反映器械设计和预期用途的代码 -B. 非能动器械 -2. 非能动非植入设备 -MDN 1211 用于消毒、清洁和冲洗的非植入式非能动设备	基于质量管理体系的符合性评估 基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI(A)	仅限于用于消毒医疗器械的溶液和擦拭巾

水平技术能力	限制
MDS 1003 使用以下材料制造的器械 动物源性组织或细胞及其衍生物制造的器械：	
MDS 1004 同时属于机械的器械，该机械定义见欧洲议会和理事会第2006/42/EC号指令第2条第2款(a)项	
MDS 1005 无菌状态下的器械：	无菌处理、环氧乙烷气体灭菌 (EOG)、湿热灭菌、辐射灭菌（伽马射线、X射线、电子束）
MDS 1006 可重复使用手术器械：	
MDS 1009 包含软件/使用软件/由软件控制的器械，包括用于控制、监测或直接影响主动或主动植入器械性能的器械 器械的设备：	
MDS 1010 具有测量功能的设备：	
MDS 1011 系统或程序中的设备 包装：	

MDS 1014	作为整体组成部分包含体外诊断设备的器械：	
横向技术能力		限制
MDT 2001	采用金属加工制造的器械：	
MDT 2002	采用塑料加工制造的设备：	
MDT 2003	采用非金属矿物加工制造的设备（如玻璃、陶瓷）：	
MDT 2004	采用非金属非矿物加工制造的设备（例如纺织品、橡胶、皮革、纸张）：	
MDT 2006	采用化学加工制造的设备：	
MDT 2008	在洁净室及相关受控环境中制造的器械：	
MDT 2009	采用人类、动物或微生物来源材料加工制造的器械 微生物来源的材料加工制造的设备：	
MDT 2010	采用电子元件制造的设备，包括通信设备：	
MDT 2011	需包装（含贴标）的设备：	
MDT 2012	需安装、翻新的设备：	