

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

**From :** Zentralstelle der Länder für  
Gesundheitsschutz bei  
Arzneimitteln und  
Medizinprodukten (ZLG)  
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**To :** **European Commission**  
GROWTH Directorate-General  
200 Rue de la Loi,  
B-1049 Brussels.  
**Other Member States**

**Reference :**

Legislation : 93/42/EEC Medical devices

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

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**Body :**

**NB 0197**

**The body is assessed according to :**

Article 16 and Annex XI of Directive 93/42/EEC, Commission Implementing Regulation (EU) No 920/2013, MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of the EC Directives on Medical Devices, Designating Authorities Handbook, DIN EN ISO/IEC 17021-1 : 2015, DIN EN ISO/IEC 17065 : 2013

**The competence of the body was assessed by :** ZLG and Joint Assessment Team according to Commission Implementing Regulation (EU) No 920/2013

**The assessment of the body covers the product categories and conformity assessment procedures concerned by this notification :** Yes

## Tasks performed by the Body :

Last approval date : 14/05/2019

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*MD 0100 - General non-active, non-implantable medical devices			
- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
*MD 0200 - Non-active implants			
- *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	excluding implants for full replacement of the hip, shoulder, knee
- *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC declaration of conformity (product quality assurance)		
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding hyperbaric therapy chambers
- *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding devices for stimulating the brain
- *MD 1104 - Active surgical devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1105 - Active ophthalmologic devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1106 - Active dental devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system EC type-examination	Annex II Annex III	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
- *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1111 - Software	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system	Annex II	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	
- *MD 1403 - Devices for hyperthermia / hypothermia	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

Horizontal technical competence	Limitations
*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	
*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)	
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	for active medical devices only
*MDS 7006 - Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants
*MDS 7007 - Medical devices utilising micromechanics	
*MDS 7008 - Medical devices utilising nanomaterials	
*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed	
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	