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

From : Agence Fédérale des Médicaments et des Produits de Santé (AFMPS) - Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)
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To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
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Other Member States

Reference : Legislation : 93/42/EEC Medical devices

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

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Body : **NB 1639**

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

Name of National Accreditation Body (NAB) : BELAC - Belgian Accreditation Body

The accreditation covers the product categories and conformity assessment procedures concerned by this notification : Yes

Tasks performed by the Body :

Last approval date : 22/12/2016

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	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to accessories (e.g. lubricants etc) and male/female condoms. No diaphragm's or IUD's
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to devices such as receptacles, petri dishes, pipettes or syringes. No media, substances or mixture of substances.
*MD 0200 - Non-active implants			
- *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. No joints (partial or complete).
- *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to implantable holders used in radiotherapy (brachytherapy) and class IIb spinal Implants, spinal stents and cervical cage.
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to clamps and staples.
- *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC declaration of conformity (production quality assurance)		
- *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Limited to crowns, prostheses and bridges.
*MD 1100 - General active medical devices			
- *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. Only parts (e.g. connectors, flow meters, Venturi, plastic tubing,…). No complete gas supply systems. No medical glasses.
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.
- *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices. No devices intended for the monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient.
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V	No class III medical devices.

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC declaration of conformity (production quality assurance)		
- *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	No class III medical devices.

Horizontal technical competence	Limitations
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	No class III medical devices.
*MDS 7006 - Medical devices in sterile condition	No class III medical devices. For ETO, irradiation, moist heat, aseptic process and clean rooms technologies
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	No class III medical devices.