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

From : ANSM : Agence Nationale de Sécurité du Médicament et des produits de santé - Direction de l'Inspection
143, 147, Boulevard Anatole France
93285 SAINT-DENIS CEDEX
France

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 :

GMED
1, rue Gaston Boissier
75015 PARIS
France
Phone : +33 1 40 43 37 00
Fax : + 33 1 40 43 37 37
Email : info@lne-gmed.com
Website : www.gmed.fr

Body : **NB 0459**

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

Name of National Accreditation Body (NAB) : COFRAC - Comité Français d'Accréditation

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

Tasks performed by the Body :

Last approval date : 03/08/2018

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 EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	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 0103 - Non-active orthopaedic and rehabilitation 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 0104 - Non-active medical devices with measuring function	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 0105 - Non-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 0106 - Non-active instruments	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 0107 - Contraceptive medical 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 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	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 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (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 0110 - Non-active medical devices for ingestion	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 0200 - Non-active implants			
- *MD 0201 - Non-active cardiovascular implants	EC type-examination EC verification	Annex III Annex IV	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	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	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 0203 - Non-active functional implants	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 0204 - Non-active soft tissue implants	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 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	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 0302 - Suture material and clamps	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 0303 - Other medical devices for wound care	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 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	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 0402 - Dental materials	EC type-examination EC verification	Annex III Annex IV	

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	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 0403 - Dental implants	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 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	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 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	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 1103 - Devices for stimulation or inhibition	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 1104 - Active surgical devices	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 1105 - Active ophthalmologic devices	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 1106 - Active dental devices	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 1107 - Active devices for disinfection and sterilisation	EC type-examination EC verification EC declaration of conformity	Annex III Annex IV Annex II	

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

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
- *MD 1302 - Monitoring devices of vital physiological parameters	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 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	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 1402 - Devices utilising non-ionizing radiation	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 1403 - Devices for hyperthermia / hypothermia	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 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	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	

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	
*MDS 7006 - Medical devices in sterile condition	Chemical sterilization/Dry heat sterilization/Hydrogen peroxid with or without plasma process sterilization/Ultra High Temperature Infusion sterilization process
*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	