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

From : Ministero dello Sviluppo Economico - Direzione Generale per il Mercato, la Concorrenza, il Consumatore, la Vigilanza e la Normativa Tecnica
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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 0373**

The body is assessed according to :

EN ISO/IEC 17020 - Inspection

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17065 - Product certification

The competence of the body was assessed by : MINISTERO DELLA SALUTE - MINISTERO DELLO SVILUPPO ECONOMICO

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 : 24/07/2017

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	
- *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	
- *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	
- *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	
- *MD 0105 - Non-active ophthalmologic devices	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	Annex III limited to ophthalmic solutions
- *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *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	
- *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
*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)	Annex II Annex V	
- *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	
- *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	Annex III limited to injectable visco-elastic solutions for intra-articular use
- *MD 0204 - Non-active soft tissue implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	Annex III limited intradermal fillers
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity	Annex II Annex V	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	(production quality assurance)		
- *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	
- *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	
*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)	Annex II Annex V	
- *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
*MD 1100 - General active medical devices			
- *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system)	Annex II	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification	Annex III Annex IV	Limited to accelerator for hadron therapy and related dose delivery system

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 7006 - Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam, moist heat sterilisation, radiation sterelisation (gamma, electron beam)
*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	