

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

From : Medical Devices Competent Authority - Medical and Public Health Services
Prodromou 1 & Chilonos 17
Corner
1449 Nicosia
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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 2803

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The body is assessed according to :

Commission Implementing Regulation (EU) No 920/2013

The competence of the body was assessed by : Cyprus Designation Authority and Joint Assessment Team

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

Tasks performed by the Body :

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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	Except 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	Except 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	Except 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	Except Class III Medical Devices
- *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except 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	Except 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	Male Condoms only
- *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	Except Class III Medical Devices
*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	
*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	
- *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 0400 - Non-active dental devices and accessories			
- *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 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Respiratory Devices only, Except Class III Medical Devices
- *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V	Except 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 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except 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	Except 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	Except Class III Medical Devices
*MD 1300 - Monitoring 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	Except Class III Medical Devices

Horizontal technical competence	Limitations
*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	
*MDS 7006 - Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilization (EOG), moist heat sterilization, radiation sterilization
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	