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
Via Sallustiana, 53
00187 ROMA
Italy

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 :

BUREAU VERITAS ITALIA S.P.A.
Viale Monza, 347
20126 - MILANO (MI)
Italy
Phone : +39 02 270911
Fax : +39 02 2552980
Email : info.bv.italia@it.bureauveritas.com
Website : www.bureauveritas.it

Body : **NB 1370**

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 : 06/05/2019

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	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	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
- *MD 0106 - Non-active 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	Exclusion of class III medical devices
- *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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
- *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	Exclusion of class III medical devices
*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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
- *MD 0303 - Other medical devices for wound care	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	Exclusion of 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) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *MD 0402 - Dental materials	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	Exclusion of class III medical devices
- *MD 0403 - Dental 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	Exclusion of class III medical devices
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	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	Exclusion of class III 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices - excluding hyperbaric chambers for oxygen therapy
- *MD 1103 - Devices for stimulation or inhibition	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	Exclusion of class III medical devices
- *MD 1104 - Active surgical 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	Exclusion of class III medical devices
- *MD 1106 - Active dental 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	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
- *MD 1111 - Software	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	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
*MD 1200 - Devices for imaging			

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *MD 1201 - Imaging devices utilising ionizing radiation	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	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of 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) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1403 - Devices for hyperthermia / hypothermia	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	Exclusion of class III medical devices

Horizontal technical competence	Limitations
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7006 - Medical devices in sterile condition	Including ethylene oxide gas sterilization (EOG), moist heat sterilization, radiation sterilization (gamma, x-ray, electron beam), low temperature steam.
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	