

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

**From :** The Norwegian Medicines Agency  
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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 :**

DNV Product Assurance AS  
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**Body :**

**NB 2460**

**The body is formally accredited against :**

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17065 - Product certification

**Name of National Accreditation Body (NAB) :** NA (Norsk Akkreditering)

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

## Tasks performed by the Body :

Last approval date : 13/02/2017

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 declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *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 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	
*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 declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 0204 - Non-active soft tissue 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	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *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 verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex II Annex V	
- *MD 0402 - Dental materials	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV 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 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *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	
- *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	
- *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *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	
- *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	
- *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	
- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1112 - Medical gas supply systems and parts thereof	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 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	
- *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	
*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	
- *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	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *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	
- *MD 1404 - Devices for (extracorporeal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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 7003 - Medical devices incorporating derivatives of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC	
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7006 - Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others.
*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	