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

From : Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Gruppe 2.1 "Produktbeschaffenheit, Grundsatzfragen"
Friedrich-Henkel-Weg 1-25
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To : **European Commission**
Enterprise Directorate-General
-
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 0044**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 04/06/2013

Period of validity of the notification :

Valid until : Unlimited

The body is formally accredited against :

Artikel 16 und Anhang XI der Richtlinie 93/42/EWG MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of the EC Directives on Medical Devices (http://ec.europa.eu/enterprise/medical_devices/meddev/2_10_2date04_2001.pdf) Handbuch für benennende Behörden/ Designating Authorities Handbook (http://ec.europa.eu/enterprise/medical_devices/nb/da_handbook_de.pdf) DIN EN ISO/IEC 17021 : 2006 DIN EN 45011 : 1998 DIN EN ISO/IEC 17025 : 2005

Name of National Accreditation Body (NAB) : DAkkS - Deutsche Akkreditierungsstelle GmbH

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

Tasks performed by the Body :

Created : 25/05/2009 **| Last update :** 06/05/2010

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 Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0107 - Contraceptive medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 0200 - Non-active implants			
- *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0402 - Dental materials	Full quality assurance system	Annex II	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	Production quality assurance Product quality assurance	Annex V Annex VI	
- *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	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 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	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	Except hyperbaric chambers
- *MD 1103 - Devices for stimulation or inhibition	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 1104 - Active surgical 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 1105 - 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 1106 - Active dental 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 1107 - Active devices for disinfection and sterilisation	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 1108 - Active rehabilitation devices and active prostheses	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 1109 - Active devices for patient positioning and transport	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 1111 - Software	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 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification	Annex II Annex III Annex IV	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	Production quality assurance Product quality assurance	Annex V Annex VI	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	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 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	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 1302 - Monitoring devices of vital physiological parameters	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 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	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 1402 - Devices utilising non-ionizing radiation	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	

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	For active medical devices only
*MDS 7006 - Medical devices in sterile condition	
*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed	