

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

From : Ministry of Economy - Innovation
and Industrial Department
Plac Trzech Krzyzy 3/5
00-507 Warszawa
Poland

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 :

TUV NORD Polska Sp. z o.o
ul. Mickiewicza 29
40-085 Katowice
Poland
Phone : +48 32 7864646
Fax : +48 32 7864601
Email : biuro@tuv-nord.pl
Website : www.tuv-nord.pl

Body :

NB 2274

Created : 27/10/2010 | **Last update :** 22/10/2012

Period of validity of the notification :

Valid until : 01/03/2014(Expired/Withdrawn)

The body is assessed according to :

Law on Medical Product

The competence of the body was assessed by : Experts of Ministry of Health - one of them has attended in Designation Authority Assessor Course; two of them are experienced in QMS and they are QMS auditors

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

Tasks performed by the Body :

Created : 07/02/2012 | Last update : 09/10/2012

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 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 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	only infusion pumps
- *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1111 - Software	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

Horizontal technical competence	Limitations
*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7005 - Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)	
*MDS 7006 - Medical devices in sterile condition	