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
D-44149 Dortmund
Germany

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 :

TÜV NORD CERT GmbH
Langemarckstraße 20
45141 ESSEN
Germany
Phone : +49 (0) 201 825-3335
Fax : +49 (0) 201 825-3290
Email : info@tuev-nord.de
Website : www.tuev-nord-cert.de

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 assessed according to :

EN 45012 - EN ISO/IEC 17021

EN 45011 - EN ISO/IEC 17065

EN 45001 - EN ISO/IEC 17025

The competence of the body was assessed by :

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

Tasks performed by the Body :

Created : 08/07/2008 **| Last update :** 05/09/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Active medical devices, except			
- hyperbaric therapy chambers	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	
- hyperthermy 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	
- medical supply units	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	
- 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	
Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V	
Non-active medical 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	