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**
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 :

MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH
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Website : http://www.medcert.de

Body : **NB 0482**

The body is assessed according to :

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17025 - Testing and calibration laboratories

EN ISO/IEC 17065 - Product certification

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 :

Last approval date : 12/09/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Active medical devices, except			
- x-ray diagnostic devices for CT and angiographie; MR-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 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	