

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 : 90/385/EEC Active implantable medical devices

Body name, address, telephone, fax, email, website :

MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH
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20355 HAMBURG
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Email : info@medcert.de
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 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 : 15/09/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Fillingsets for implantable pump	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	