# 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 : 90/385/EEC Active implantable medical devices

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

MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH
Pilatuspool 2
20355 HAMBURG
Germany
Phone : +49:40:22633250
Fax : +49:40:226332515
Email : info@medcert.de
Website : http://www.medcert.de

**Body :** **NB 0482**

**Created :** Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 08/09/2010

**Period of validity of the notification :**

Valid until : Unlimited

**The body is formally accredited against :**

Article 11 and Annex 8 of Directive 90/385//EEC MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of the EC Directives on Medical Devices Designating Authorities Handbook 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 :** 15/09/2008 **| Last update :** 22/04/2010

| Product family, product /Intended use/Product range | Procedure/Modules | Annexes or articles of the directives | Limitations |
|---|---|---|---|
| *AIMD 0100 - General active implantable medical devices | | | |
| - *AIMD 0102 - Active implantable medical devices delivering drugs or other substances | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | refill kits for implantable pumps |

| Horizontal technical competence | Limitations |
|---|---|
| *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | |
| *MDS 7006 - Medical devices in sterile condition | |