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 :

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Body : **NB 0197**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 18/09/2014

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 : 12/09/2008 **| 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 0101 - Active implantable medical devices for stimulation / inhibition	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	
- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	
- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	

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