Notification of a Body in the framework of a technical harmonization directive

From : Bundesministerium für Gesundheit - Department Pharmaceuticals and Medical Devices - III/3
Radetzkystrasse 2
A-1030 Wien
Austria

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 :

PRÜFSTELLE FÜR MEDIZINPRODUKTE GRAZ
Kopernikusgasse 24/1
8010 GRAZ
Austria
Phone : +43/316.873-7397
Fax : +43/316.873-4412
Email : norbert.leitgeb@tugraz.at
Website :

Body : **NB 0636**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 19/09/2012

Period of validity of the notification :

Valid until : Unlimited

The body is formally accredited against :

EN 45012 - EN ISO/IEC 17021

EN 45001 - EN ISO/IEC 17025

Name of National Accreditation Body (NAB) : BMWFJ - Bundesministerium für Wirtschaft, Familie und Jugend

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

Tasks performed by the Body :

Created : 04/09/2012 **| Last update :** 19/09/2012

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) EC type-examination EC verification	Annex 2 Annex 5 Annex 3 Annex 4	
- *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) EC type-examination EC verification	Annex 2 Annex 5 Annex 3 Annex 4	
- *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) EC type-examination EC verification	Annex 2 Annex 5 Annex 3 Annex 4	

Horizontal technical competence	Limitations
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7006 - Medical devices in sterile condition	
*MDS 7007 - Medical devices utilising micromechanics	