

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

**From :** Ministry of Health and Welfare,  
Department GMT  
PO Box 20350  
2500 EJ Den Haag  
Netherlands

**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 :**

BSI Group The Netherlands B.V.  
Say Building, John M. Keynesplein 9, 1066 EP  
Amsterdam  
Netherlands  
Phone : +31 (0)20 346 07 80  
Fax :  
Email : info.nl@bsigroup.com  
Website :

**Body :**

**NB 2797**

**The body is formally accredited against :**

EN ISO/IEC 17021 - Certification of management systems

**Name of National Accreditation Body (NAB) :** RVA (RvA)

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

## Tasks performed by the Body :

Last approval date : 06/12/2018

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 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC	
*MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)	
*MDS 7003 - Medical devices incorporating derivatives of human blood according to Directive 2000/70/EC, amended by Directive 2001/104/EC	
*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	
*MDS 7008 - Medical devices utilising nanomaterials	
*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed	
*MDS 7010 - Medical devices incorporating software / utilising software / controlled by software	