# 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 :**

DEKRA Certification B.V.
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**Body :** **NB 0344**

**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 :** 24/01/2019

| 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)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |
| - *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)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |
| - *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality)<br>EC type-examination<br>EC verification | Annex 2<br>Annex 5<br>Annex 3<br>Annex 4 | |

| 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 derivates 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 absorbd | |
| *MDS 7010 - Medical devices incorporating software / utilising software / controlled by software | |