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

From : Health Products Regulatory Authority
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Ireland

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 :

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Body : **NB 0050**

The body is assessed according to :

EU Implementing Regulation 666 of 2020 amending EU Implementing Regulation 920 of 2013 Article 11 and Annex 8 of Directive 90/385/EEC

The competence of the body was assessed by : Health Products Regulatory Authority

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

Tasks performed by the Body :

Last approval date : 12/02/2021

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	limited to cardiac assist & circulatory support devices

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 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	