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

From : Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
Heinrich-Böll-Ring 10
53119 Bonn
Germany

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 :

TÜV Rheinland LGA Products GmbH
Tillystraße 2
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Germany
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Body : **NB 0197**

The body is assessed according to :

Article 11 and Annex 8 of Directive 90/385/EEC, Commission Implementing Regulation (EU) No 920/2013, 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 17021-1 : 2015, DIN EN ISO/IEC 17065 : 2013

The competence of the body was assessed by : ZLG and Joint Assessment Team according to Commission Implementing Regulation (EU) No 920/2013

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 : 14/05/2019

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) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	products for stimulation only, excluding brain stimulation and cardiac pacemakers

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 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7006 - Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants
*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	