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

From : Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
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Germany

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference : Legislation : 93/42/EEC Medical devices

Body name, address, telephone, fax, email, website :

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Body : **NB 0681**

The body is assessed according to :

Article 16 and Annex XI of Directive 93/42/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 : 2011 / 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 : 08/06/2017

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*MD 0100 - General non-active, non-implantable medical devices			
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
*MD 1100 - General active medical devices			
- *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
- *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)

Horizontal technical competence	Limitations
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	