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

From : National Institute of Pharmacy and Nutrition (OGYÉI)
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Hungary

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 :

CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft.
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Body : **NB 2409**

The body is assessed according to :

EU Regulation 920/2013, Directive 90/385/EEC, national legislation 4/2009 (III. 17.) Decree of the Minister of Health on medical devicesand and NBOG Designating Authorities Handbook and guidelines.

The competence of the body was assessed by : OGYÉI (National Institute of Health and Nutrition)

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 : 08/09/2020

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	

Horizontal technical competence	Limitations
*MDS 7001 - Medical devices incorporating medicinal substances according to Directive 2001/83/EC	regarding Annex 2 or 5
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	regarding Annex 2 or 5
*MDS 7006 - Medical devices in sterile condition	regarding Annex 2 or 5 Including aseptic processing, ethylene oxide gas sterilisation (EOG), radiation sterilization (gamma,x-ray, electron beam), moist heat sterilization
*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd	regarding Annex 2 or 5
*MDS 7010 - Medical devices incorporating software / utilising software / controlled by software	regarding Annex 2 or 5