

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

Other Member States

Reference:

Legislation: Regulation (EU) 2017/745 on medical devices

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

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Body info:

NB 3022

Body:

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Tasks performed by the Body:

Last approval date: 2023-11-25

Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	

Horizontal technical competences	Limitations
MDS 1010 Devices with a measuring function:	
MDT 2011 Devices which require packaging, including labelling:	
MDT 2012 Devices which require installation, refurbishment:	