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

From:

Ministriy of Trade – DG Product Safety and Inspection
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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 :

Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim Şirketi
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Body info:

NB 2764

Body:

Created: 2019-01-03

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Name of National Accreditation Body (NAB):

TURKAK (Turkish Accreditation Agency)

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

Tasks performed by the Body:

Last approval date: 2020-11-19

Products	Procedures	Articles /Annexes	Limitations
-*MD 0100 - General non-active, non-implantable medical devices -*MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0100 - General non-active, non-implantable medical devices -*MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0100 - General non-active, non-implantable medical devices -*MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0100 - General non-active, non-implantable medical devices -*MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0100 - General non-active, non-implantable medical devices -*MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0200 - Non-active implants -*MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Only felts and similar technologies
-*MD 0200 - Non-active implants -*MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0200 - Non-active implants -*MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0200 - Non-active implants -*MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0300 - Devices for wound care -*MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0300 - Devices for wound care -*MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0300 - Devices for wound care -*MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

Products	Procedures	Articles /Annexes	Limitations
-*MD 0400 - Non-active dental devices and accessories -*MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0400 - Non-active dental devices and accessories -*MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 0400 - Non-active dental devices and accessories -*MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 1100 - General active medical devices -*MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Only infusion devices
-*MD 1100 - General active medical devices -*MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	excluding hyperbaric chambers for oxygen therapy
-*MD 1100 - General active medical devices -*MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 1100 - General active medical devices -*MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 1300 - Monitoring devices -*MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 1300 - Monitoring devices -*MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
-*MD 1400 - Devices for radiation therapy and thermo therapy -*MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

Horizontal technical competences	Limitations
***MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC:**	
***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, x-ray, electron beam)

Horizontal technical competences	Limitations
***MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed:**	
***MDS 7010 - Medical devices incorporating software /utilising software /controlled by software:**	