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

From : Ministry of Economy – DG
Product Safety and Inspection
Inönü Bulvari No:36 Emek 06100
Ankara
Turkey

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 :

Szutest Uygunluk De#erlendirme A.#.
Tatl#su Mahallesi Akif #nan Sk. No:1/1 Ümraniye / #stanbul
#STANBUL
Turkey
Phone : 00 90 216 469 46 66
Fax : 00 90 216 469 46 67
Email : info@szutest.com.tr
Website : www.szutest.com.tr

Body : **NB 2195**

The body is formally accredited against :

EN 45012 - EN ISO/IEC 17021

Name of National Accreditation Body (NAB) : Turkish Accreditation Agency (TURKAK)

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

Tasks performed by the Body :

Last approval date : 27/07/2016

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 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 0200 - Non-active implants			
- *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0402 - Dental materials	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0403 - Dental implants	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance	Annex II Annex V	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1111 - Software	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	

Horizontal technical competence	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	
*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	