# 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**
Enterprise Directorate-General
-
B 1049 Brussels

**Other Member States**

**Reference :** Legislation : 93/42/EEC Medical devices

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

Alberk QA Uluslararas# Teknik Kontrol ve Belgelendirme Anonim #irketi
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**Body :** **NB 2138**

**Created :** 27/01/2009 **| Last update :** 06/06/2013

**Period of validity of the notification :**

Valid until : 31/12/2099

**The body is formally accredited against :**

EN 45004 - EN ISO/IEC 17020

EN 45012 - EN ISO/IEC 17021

EN 45011 - EN ISO/IEC 17065

**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 :**

**Created :** 29/06/2011 **| Last update :** 27/10/2011

| 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 | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0103 - Non-active orthopaedic and rehabilitation devices | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0104 - Non-active medical devices with measuring function | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0105 - Non-active ophthalmologic devices | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0106 - Non-active instruments | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 0200 - Non-active implants | | | |
| - *MD 0201 - Non-active cardiovascular implants | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0202 - Non-active orthopaedic implants | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0203 - Non-active functional implants | EC declaration of conformity (full quality assurance system) | Annex II | |

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|---|---|---|---|
| | EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex V<br>Annex VI | |
| - *MD 0204 - Non-active soft tissue implants | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 0300 - Devices for wound care | | | |
| - *MD 0301 - Bandages and wound dressings | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0302 - Suture material and clamps | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0303 - Other medical devices for wound care | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 0400 - Non-active dental devices and accessories | | | |
| - *MD 0401 - Non-active dental equipment and instruments | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0402 - Dental materials | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 0403 - Dental implants | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 1100 - General active medical devices | | | |
| - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1103 - Devices for stimulation or inhibition | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1104 - Active surgical devices | EC declaration of conformity | Annex II | |

| Product family, product /Intended use/Product range | Procedure/Modules | Annexes or articles of the directives | Limitations |
|---|---|---|---|
| | (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex V<br>Annex VI | |
| - *MD 1105 - Active ophthalmologic devices | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1106 - Active dental devices | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1107 - Active devices for disinfection and sterilisation | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1108 - Active rehabilitation devices and active prostheses | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1109 - Active devices for patient positioning and transport | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1111 - Software | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 1200 - Devices for imaging | | | |
| - *MD 1201 - Imaging devices utilising ionizing radiation | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1202 - Imaging devices utilising non-ionizing radiation | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| *MD 1300 - Monitoring devices | | | |
| - *MD 1301 - Monitoring devices of non-vital physiological parameters | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1302 - Monitoring devices of vital physiological | EC declaration of conformity | Annex II | |

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|---|---|---|---|
| parameters | (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex V<br>Annex VI | |
| *MD 1400 - Devices for radiation therapy and thermo therapy | | | |
| - *MD 1401 - Devices utilising ionizing radiation | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1402 - Devices utilising non-ionizing radiation | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1403 - Devices for hyperthermia / hypothermia | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |
| - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) | EC declaration of conformity (full quality assurance system)<br>EC declaration of conformity (production quality assurance)<br>EC declaration of conformity (product quality assurance) | Annex II<br>Annex V<br>Annex VI | |

| Horizontal technical competence | Limitations |
|---|---|
| *MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC | |
| *MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC | |
| *MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery | |
| *MDS 7005 - Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE) | |
| *MDS 7006 - Medical devices in sterile condition | |
| *MDS 7007 - Medical devices utilising micromechanics | |
| *MDS 7008 - Medical devices utilising nanomaterials | |
| *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed | |