

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

From : Czech Institute for
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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 :

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Body :

NB 1021

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 23/10/2008

Period of validity of the notification :

Valid until : Unlimited

The body is formally accredited against :

EN 45012 - EN ISO/IEC 17021

EN 45011 - EN ISO/IEC 17065

EN 45001 - EN ISO/IEC 17025

Name of National Accreditation Body (NAB) : CAI - Czech Accreditation Institute

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

Tasks performed by the Body :

Created : 04/03/2013 | Last update : 06/06/2013

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 type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	For medical devices from textile materials or with substantial part from textile materials - Annex II, III, IV, V, VI ; For medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials - Annex II, V, VI
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	For medical devices from textile materials or with substantial part from textile materials - Annex II, III, IV, V, VI ; For medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials - Annex II, V, VI
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	For medical devices from textile materials or with substantial part from textile materials - Annex II, III, IV, V, VI ; For medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials - Annex II, V, VI
- *MD 0302 - Suture material and clamps	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	For medical devices from textile materials or with substantial part from textile materials - Annex II, III, IV, V, VI ; For medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials - Annex II, V, VI
- *MD 0303 - Other medical devices for wound care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	For medical devices from textile materials or with substantial part from textile materials - Annex II, III, IV, V, VI ; For medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials - Annex II, V, VI

Horizontal technical competence	Limitations
*MDS 7006 - Medical devices in sterile condition	Medical devices from textile materials or with substantial part from textile materials; Medical devices from rubber or plastic materials or with substantial part from rubber or plastic materials.