

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

From : European Commission
Enterprise Directorate-General
-
B 1049 Brussels

To : European Commission
Trade Directorate-General
-
B 1049 Brussels

Reference :

Directive : 93/42/EEC Medical devices

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

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Switzerland
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Type of body :

NB 1254

Created : unknown | **Last update :** 14/08/2007

Period of validity of the notification :

Valid until : Unlimited

Basis of competence assessment :

EN 45012 - EN ISO/IEC 17021

The body has :

- the required technical competence in relation to the product(s) under this directive
- sufficient competence in relation to the procedure(s)/attestation of conformity selected for these product(s)

Yes

Competence assessment performed by :

Nationally recognised accreditation body, operating according to EN 17011

The Nationally recognised accreditation body is a signatory to the following parts of the EA/MLA

Name(s) of Accreditation/Competence Assessment body :

Swiss Accreditation Service (SAS)

The nationally recognised accreditation body is a signatory to the following parts of the EA/MLA :

Calibration
Testing
Inspection
Product certification
QMS (Quality System certification)
Personnel certification
EMS (Environment management systems certification)

Tasks performed by the Body :

Created : unknown | Last update : 14/08/2007

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives
Non-active medical devices - skeleton implants - functional implants - single use medical products - reusable non-active medical instruments - surgical instruments - wound dressings and bandages - sutures and surgical clips - instruments and equipment for dentistry - dental materials - dental implants Active medical devices - patient storage and transport equipment - dental equipment - diagnostic devices without ionising radiation - measuring equipment as accessories to medical devices - prostheses and equipment for rehabilitation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI