

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 :

Legislation : 98/79/EC In vitro diagnostic medical devices

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

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Body :

NB 1250

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 07/10/2010

Period of validity of the notification :

Valid until : Unlimited

Joint Committee Decision : Date | Number

The body is formally accredited against :

EN 45012 - EN ISO/IEC 17021

EN 45011 - EN ISO/IEC 17065

Name of National Accreditation Body (NAB) : Swiss Accreditation Service (SAS)

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

Tasks performed by the Body :

Created : 03/10/2008 | Last update : 03/10/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Products referred in Annex II, list B	Full quality assurance system Production quality assurance	Annex IV Annex VII	
The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar	Full quality assurance system Production quality assurance	Annex IV Annex VII	