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

From : PERMANENT REPRESENTATION OF SWEDEN TO THE EUROPEAN UNION
1040 BRUXELLES

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 0402**

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17065 - Product certification

Name of National Accreditation Body (NAB) :

The accreditation covers the product categories and conformity assessment procedures concerned by this notification : No

Tasks performed by the Body :

Last approval date :

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
All Class I sterile devices	Production quality assurance Product quality assurance	Annex V Annex VI	
Bone anchored implants for dental and craniofacial reconstructions	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Class I devices with a measuring function	Production quality assurance Product quality assurance	Annex V Annex VI	
Diagnostic X-ray equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Electromedical diagnostic equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Equipment for anaesthesia and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Non active devices specifically intended for recording of X-ray diagnostic images. (Annex IX, 4.4. Rule 16)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Surgical instruments for single use	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	