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

From : RAPPRESENTAZIONE PERMANENTE D'ITALIA
PRESSO L'UNIONE EUROPEA
1040 BRUXELLES

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 :

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Body : **NB 0426**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 22/12/2009

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 45000

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 :

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

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Apparatus and accessories for muscle stimulation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Blood bags	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Contraceptives	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Devices for contact lens treatment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Devices for the administration to or removal from the patient's body of medicines, body fluids or other substances	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Devices for the sterilisation of medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Devices in sterile packs	Production quality assurance Product quality assurance	Annex V Annex VI	
Invasive devices for natural orifices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Invasive devices for surgical use	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Measuring devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Non-invasive devices in contact with damaged skin	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Probes and catheters for urology, gastroenterology, respiratory tracts, surgical aspiration and oxygen therapy	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Products and accessories for surgical use, such as suture needles, syringes, surgical gloves	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Single-use products			
- contact lenses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- dental equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- electrocardiographs and electroencephalographs	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- ultrasound equipment	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	