

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

**From :** Ministero delle Attivita' Produttive  
Direzione generale per lo  
sviluppo e la Competitivita'  
Via Molise, 2  
00187 ROMA  
Italy

**To :** **European Commission**  
Enterprise Directorate-General  
-  
B 1049 Brussels  
**Other Member States**

**Reference :**

Directive : 93/42/EEC Medical devices

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

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**Body :**

**NB 0051**

**Created :** Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 27/07/2009

**Period of validity of the notification :**

Valid until : 01/03/2012

**The body is designated for :**

EN 45004 - EN ISO/IEC 17020

EN 45012 - EN ISO/IEC 17021

EN 45011

EN 45001 - EN ISO/IEC 17025

**The competence of the body was assessed by :**

**The assessment of the body covers the product categories and conformity assessment procedures concerned by this notification :** Yes

## Tasks performed by the Body :

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) | Last update : 19/06/2007

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Equipment for electrosurgery and accessories Anaesthetics equipment, incubators, ventilators, oxygen therapy equipment and accessories Equipment for extracorporeal circulation, infusion, transfusion, haemophoresis and accessories Equipment for dialysis and accessories Equipment for checking and recording vital functions and accessories Cardiac and muscular stimulation equipment and accessories Dental equipment and accessories Ophtalmological equipment and accessories Equipment for aerosol therapy and accessories	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
Disposable syringes Urethral catheters, catheters for heart surgery and for the central circulatory system Bags for parenteral and enteral nutrition and accessories Auditory prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Equipment and accessories for diagnosis and treatment using ultrasound Equipment and accessories for diagnostic imaging, using ionising and non-ionising radiation Equipment and accessories for treatment using ionising and non-ionising radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
Bone nails, screws and plates (including accessories) Contraceptive products Dressings Contact lenses and solutions for contact lenses Gloves for medical use dental implants and accessories	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
equipment for cryosurgery and accessories equipment for disinfection and sterilization equipment for orthopaedic rehabilitation and accessories	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	