

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

**From :** Ministero dello Sviluppo  
Economico - Direzione Generale  
per il Mercato, la Concorrenza, il  
Consumatore, la Vigilanza e la  
Normativa Tecnica  
Via Sallustiana, 53  
00187 ROMA  
Italy

**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 0051**

**The body is assessed according to :**

**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 :

Last approval date : 19/06/2007 | Valid until : 01/03/2012(Expired/Withdrawn)

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Anaesthetics equipment, incubators, ventilators, oxygen therapy equipment 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	
Auditory prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Bags for parenteral and enteral nutrition and accessories	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Bone nails, screws and plates (including accessories)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Cardiac and muscular stimulation equipment 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	
Contact lenses and solutions for contact lenses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Contraceptive products	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Dental equipment 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Dressings	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	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	
Equipment and accessories for diagnostic imaging, 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	
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	
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	
Equipment for checking and recording vital functions and	Full quality assurance system	Annex II	

<b>Product family, product /Intended use/Product range</b>	<b>Procedure/Modules</b>	<b>Annexes or articles of the directives</b>	<b>Limitations</b>
accessories	EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	
Equipment for dialysis 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	
Equipment for electrosurgery 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	
Equipment for extracorporeal circulation, infusion, transfusion, haemophoresis 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	
Gloves for medical use	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Ophthalmological equipment 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	
Urethral catheters, catheters for heart surgery and for the central circulatory system	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
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	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	
equipment for disinfection and sterilization	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	
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	