

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
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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 1936

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Last approval date : 01/08/2007 | Valid until : 20/07/2012(Expired/Withdrawn)

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Anaesthetic and respiratory equipment	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
Contraceptive products	Full quality assurance system	Annex II	
Equipment for aerosol therapy and accessories	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
Equipment for measuring and/or monitoring and/or recording and/or analysing physiological parameters and vital functions	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
Equipment for rehabilitation	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
Infant radiant warmers	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
Medical weighing instruments	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
blood heater	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
cardiac stimulation equipment	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
dental equipment (excpt for: equipment for tartar ablation, equipment for dental diagnosis)	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
echographers	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
electrically powered heat exchangers	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
endoscopes	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
equipment for blood oxygenation in extracorporeal circulation	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
equipment for dental diagnosis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
equipment for diathermy (except for: blood heater, heat exchanger for extracorporeal circulation, infant radiant	Full quality assurance system EC type-examination	Annex II Annex III	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
warmers, electrically powered heat exchangers)	EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	
equipment for extracorporeal circulation (except for: equipment for haemodialysis, equipment for blood oxygenation in extracorporeal circulation)	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 haemodialysis	EC type-examination EC verification	Annex III Annex IV	
equipment for ionophoresis	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
equipment for medicinal gases administration	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 peritoneal dialysis	EC verification	Annex IV	
equipment for radiology	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
equipment for tartar ablation	EC verification	Annex IV	
gloves for medical use, gauzes, syringes, needles and scalpels	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
heat exchanger for extracorporeal circulation	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
incubators	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
laser scalpel, ultrasound scalpel and electric scalpel	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
muscular and neuromuscular electrostimulators	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
optic devices/equipment	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
suction pump, turbines and drills for surgical use	Full quality assurance system EC verification Production quality assurance Product quality assurance	Annex II Annex IV Annex V Annex VI	
therapeutic lasers	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	