

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

**From :** PERMANENT  
REPRESENTATION OF THE  
UNITED-KINGDOM 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 0843**

**The body is formally accredited against :**

The requirements of Annex XI of the Medical Devices Directive 93/42/EEC (MDA)  
Guidance Notes 6 - Requirements for UK Notified Bodies

**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 : 03/08/2006

<b>Product family, product /Intended use/Product range</b>	<b>Procedure/Modules</b>	<b>Annexes or articles of the directives</b>	<b>Limitations</b>
Active medical devices and their 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	
Disinfectants and surgical instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Gloves for medical use	EC verification	Annex IV	
Own Brand Labelling of all medical devices which have existing NB certification via their original manufacturer	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	
Sterile single use medical devices excluding Class III devices, ophthalmic devices, (class IIa and above) and implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
Urethral catheters	EC verification	Annex IV	
Wound dressings (Class IIa and IIb)	EC type-examination EC verification	Annex III Annex IV	