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

From : Department of Health Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road, Victoria,
London SW1W 9SZ.
United Kingdom

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 0359**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 11/07/2013

Period of validity of the notification :

Valid until : Unlimited

The body is formally accredited against :

EN 45001

Name of National Accreditation Body (NAB) : UKAS - United Kingdom Accreditation Service

The accreditation covers the product categories and conformity assessment procedures concerned by this notification : Yes

Tasks performed by the Body :

Created : 09/03/2009 **| Last update :** 22/04/2010

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC verification	Annex IV	Excluding Extracorporeal Blood Treatment Equipment
- *MD 1103 - Devices for stimulation or inhibition	EC verification	Annex IV	Excluding Defibrillators
- *MD 1104 - Active surgical devices	EC verification	Annex IV	Excluding Electrosurgical Equipment
- *MD 1105 - Active ophthalmologic devices	EC verification	Annex IV	
- *MD 1106 - Active dental devices	EC verification	Annex IV	
- *MD 1107 - Active devices for disinfection and sterilisation	EC verification	Annex IV	
- *MD 1108 - Active rehabilitation devices and active prostheses	EC verification	Annex IV	
- *MD 1109 - Active devices for patient positioning and transport	EC verification	Annex IV	
- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC verification	Annex IV	
- *MD 1111 - Software	EC verification	Annex IV	For Class IIa Devices only
*MD 1200 - Devices for imaging			
- *MD 1202 - Imaging devices utilising non-ionizing radiation	EC verification	Annex IV	Excluding Laser Devices Excluding Radionuclide and Magnetic Resonance Imaging
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	EC verification	Annex IV	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1402 - Devices utilising non-ionizing radiation	EC verification	Annex IV	
- *MD 1403 - Devices for hyperthermia / hypothermia	EC verification	Annex IV	
- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC verification	Annex IV	

Horizontal technical competence	Limitations
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*MDS 7006 - Medical devices in sterile condition	