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

From : Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin, Gruppe 2.1
"Produktbeschaffenheit,
Grundsatzfragen"
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund
Germany

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 :

Bureau Veritas Consumer Products Services Germany GmbH
Wilhelm-Hennemann-Straße 8
19061 Schwerin
Germany
Phone : +49 40 74041 0
Fax :
Email : certification.deu@bureauveritas.com
Website : www.bureauveritas.de/home/about-us/our-business/consumer_products/unsere-dienstleistungen

Body : **NB 2004**

The body is assessed according to :

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17025 - Testing and calibration laboratories

EN ISO/IEC 17065 - Product certification

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 : 11/09/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
devices for extracorporal circulation, infusions and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
electric power supply for active medical devices	EC type-examination EC verification	Annex III Annex IV	
equipment for measuring and/or recording and/or analysing vital functions	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	
respiratory devices, devices for for oxygen therapy and inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
software	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	
stimulators	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	
surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	