

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**
Enterprise Directorate-General
-
B 1049 Brussels
Other Member States

Reference :

Directive : 93/42/EEC Medical devices

Body name, address, telephone, fax, email, website :

DEKRA Certification GmbH
Handwerkstraße 15
70565 STUTTGART
Germany
Phone : +49 7 11 / 78 61 25 66
Fax : +49 7 11 / 78 61 26 15
Email : info@dekra-certification.com
Website : http://www.dekra.de

Type of body :

NB 0124

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 21/04/2009

Period of validity of the notification :

Valid until : Unlimited

Basis of competence assessment :

EN ISO/IEC 17025

EN 45012 - EN ISO/IEC 17021

EN 45011

The body has :

- the required technical competence in relation to the product(s) under this directive
- sufficient competence in relation to the procedure(s)/attestation of conformity selected for these product(s)

Yes

Competence assessment performed by :

Designating Authority

Name of the designating authority :

Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten - ZLG

Tasks performed by the Body :

Created : 09/07/2008 | Last update : 11/09/2008

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives
Non-active medical devices Active medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI
Male condoms	EC type-examination EC verification	Annex III Annex IV
Medical devices covered by directive 2003/32/EC	Full quality assurance system Production quality assurance	Annex II Annex V
non-active medical devices with already existing EC type examination certificate	EC type-examination	Annex III
Active medical devices, except - disinfection and sterilization equipment - devices for extracorporeal circulation, haemopheresis - devices for oxygen therapy and inhalation anaesthesia - devices for radiotherapy utilizing ionizing rays - ophthalmologic devices - rehabilitation devices and active protheses - respiratory devices	EC type-examination EC verification	Annex III Annex IV