

# 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 : 98/79/EC In vitro diagnostic 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 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 : Unknown (Notifications pre-dating 2006 are not available in these lists) | Last update : 10/07/2008

<b>Product family, product /Intended use/Product range</b>	<b>Procedure/Modules</b>	<b>Annexes or articles of the directives</b>
Devices for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII
The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII