

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

**From :** Bundesanstalt für Arbeitsschutz  
und Arbeitsmedizin, Gruppe 2.1  
"Produktbeschaffenheit,  
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Germany

**To :** **European Commission**  
Enterprise Directorate-General  
-  
B 1049 Brussels  
**Other Member States**

**Reference :**

Legislation : 98/79/EC In vitro diagnostic medical devices

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

TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg  
Germany  
Phone : +49 (0) 911 655-4110  
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Website : www.tuv.com/safety

**Body :**

**NB 0197**

**Created :** Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 18/09/2014

**Period of validity of the notification :**

Valid until : Unlimited

**The body is assessed according to :**

EN 45012 - EN ISO/IEC 17021

EN 45011 - EN ISO/IEC 17065

**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 :**

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>	<b>Limitations</b>
Devices for self-testing	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
Products referred in Annex II, list A	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
Products referred in Annex II, list B	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	