

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
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Germany

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
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
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Website : www.tuv.com/safety

Body :

NB 0197

The body is assessed according to :

EN ISO/IEC 17021 - Certification of management systems
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 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	