# 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 : 90/385/EEC Active implantable medical devices

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
Phone : +49 (0) 9116555225
Fax : +49 (0) 9116555226
Email : service@de.tuv.com
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 :** 12/09/2008

| Product family, product /Intended use/Product range | Procedure/Modules | Annexes or articles of the directives | Limitations |
|---|---|---|---|
| All active implantable medical devices | EC declaration of conformity (complete quality assurance system)<br>EC declaration of conformity to type (assurance of production quality) | Annex 2<br>Annex 5 | |