

**APPROVAL**  
**EC Directive 93/42/EEC Annex II, Article 3**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60037345 0001

**Report No.:** 21159091 001

**Manufacturer:** Happersberger otopront GmbH  
Langgasse 90  
65329 Hohenstein  
Deutschland

**Scope:** Design/development and production of medical devices  
(see attachment for products included)

Replaces Approval, Registration No.: HD 60020251 0001

**Date of Expiry:** 24.01.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body



Date 25.01.2011

Dipl.-Ing. D. Meier

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

**CE** The CE marking may be used if all relevant and effective EC Directives are complied with. **CE**