

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

Registration No.: HD 60039787 0001

Report No.: 21168414 002

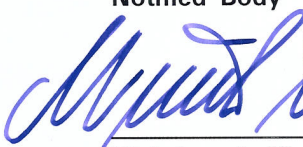

**Manufacturer:** Gyrus Medical GmbH  
Gotenstr. 3  
78532 Tuttlingen  
Deutschland

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

**Date of Expiry:** 13.07.2015

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.

Date 04.07.2011

Notified Body  
  
Dipl.-Ing. I. Munkler  


**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

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
**Registration No.:** HD 60039787 0001  
**Report No.:** 21168414 002

**Manufacturer:** Gyrus Medical GmbH  
Gotenstr. 3  
78532 Tuttlingen  
Deutschland

**Scope:** Products included:

Surgical Instruments:


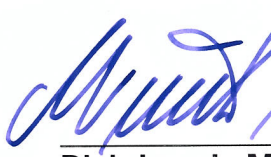
- Drills
- Polisher
- Saws
- Forceps
- RF surgical instruments
- Instruments with suction irrigation
- Resectoscopes (work elements without electrodes)

Endoscopes:

- Laryngoscopes
- Nasoscopes
- Oscopes
- Rhinoscopes
- Bronchoscopes

**Date** 04.07.2011

**Certification Body**



**Dipl.-Ing. I. Munkler**