

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60097512 0001

**Report No.:** 21221819 002

**Manufacturer:** medentis medical GmbH  
Gartenstr. 12  
53507 Dernau  
Deutschland

**Products:** Products related to dental implantology  
(see attachment for products and sites included)  
Replaces Approval, Registration no.: HD 60027766 0001

**Expiry Date:** 2019-12-03

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2014-12-08

**Date:** 2014-12-08

Notified Body

*Dr. K. Kluge*  
Dr. K. Kluge



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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

**Attachment to  
Certificate**

**Registration No.:** HD 60097512 0001  
**Report No.:** 21221819 002

**Manufacturer:** medentis medical GmbH  
Gartenstr. 12  
53507 Dernau  
Deutschland

**Products included:**

- Dental Implants
- Dental Abutments
- Dental Drills
- Healing Caps, dental
- Cover Screws, dental

**Date:** 2014-12-08

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**



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

**Attachment to  
Certificate**

**Registration No.:** HD 60097512 0001  
**Report No.:** 21221819 002

**Manufacturer:** medentis medical GmbH  
Gartenstr. 12  
53507 Dernau  
Deutschland

**Sites included:**

- medentis medical GmbH  
Römerstraße 28  
53507 Dernau, Germany

**Activities:**

Design and development, manufacture and distribution

- medentis medical GmbH  
Industriegebiet an der Bundesstraße 2  
53507 Dernau, Germany

**Activities:**

Design and development, manufacture

**Notified Body**

**Date:** 2014-12-08

*Dr. K. Kluge*  
**Dr. K. Kluge**

