

## **EC** Certificate

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

Registration No.: HD 60124858 0001

Report No.: 21221819 009

Manufacturer: medentis medical GmbH

Walporzheimer Str. 48-52

53474 Bad Neuenahr-Ahrweiler

Deutschland

**Products:** Products related to dental implantology

(see attachment for products and sites included)

Replaces Approval, Registration no.: HD 60097512 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: 2017-12-07

Date: 2017-12-07

**Notified Body** 

Dr. K. Kluge

TÜVRheinla

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

Doc. 1/1, Rev. 0

Attachment to Certificate

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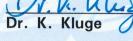
### Products included:

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

### Site included:

medentis medical GmbH Max-Planck-Str. 5-7 53501 Grafschaft, Germany

**Notified Body** 



Date: 2017-12-07