TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60124858 0001
Report No.: 21221819 009

Manufacturer:
medentis medical GmbH
Walporzheimer Str. 48-52
53474 Bad Neuenahr-Ahrweiler
Deutschland

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-12-07

Dr. K. Kluge