TÜVRheinland®

EC Certificate

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

Registration No.: HD 60141453 0001

Report No.: 21221819 020

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 60124858 0001

Expiry Date: 2024-05-26

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.

Notified Body

Effective Date: 2019-08-21

Date: 2019-08-21

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. F. Schwingen

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60141453 0001
Report No.: 21221819 020

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: 2019-08-21

Dipl.-Ing. F. Schwingen