

EC Certificate



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

Registration No.: HD 1753171-1

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

Products: Products related to dental implantology

Products included:

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

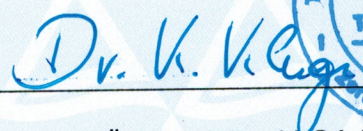
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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.

Report No.: 3334254-100

Effective date: 2021-03-31

Expiry date: 2024-05-26

Issue date: 2021-03-31



Dr. K. Kluge
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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Germany

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Instruments for dental impression

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A circular blue seal with the text "TÜV Rheinland LGA Products GmbH" around the perimeter and the TÜV Rheinland logo in the center.
Dr. K. Kluge
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The scope of certification includes the following manufacturing sites:

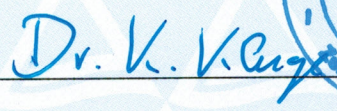
No.	Location	Product groups manufactured
/01	medentis medical GmbH Walporzheimer Str. 48-52 53474 Bad Neuenahr-Ahrweiler Germany	Products related to dental implantology
/02	Medentis Medical GmbH Max-Planck-Str. 5-7 53501 Grafschaft Germany	Products related to dental implantology

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The seal of TÜV Rheinland LGA Products GmbH, featuring a circular design with the company name and the TÜV Rheinland logo in the center.

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