

# 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



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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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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

TÜV Rheinland

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The scope of certification includes the following manufacturing sites:

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

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