

# EU Certificate

Quality Management System  
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,  
Section 2 and 3 and Chapter III



Registration No.: HZ 1753171-1

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

EUDAMED Single  
Registration No.: DE-MF-000007754

Products: Products of Class IIb:  
Odontological Protheses  
- P010201 - Dental Implants and Accessories

Products of class I, sterile:  
- Q010207 - Dental Impression Devices for Prosthetic Dentistry

The scope of certification is limited to the aspects relating to establishing, securing  
and maintaining sterile conditions

Authorised  
representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1092714-40

Effective date: 2023-08-31

Expiry date: 2028-08-30

Issue date: 2023-08-31



A handwritten signature in blue ink, appearing to read 'Dr. T. Kießling'.



Dr. T. Kießling  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certificate	2023-08-31

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