

# EU Quality Management System Certificate

We hereby certify the company

**MEDEALIS GmbH**  
**Im Steinböhl 9**  
**69518 Abtsteinach**  
**Germany**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

## **Annex IX – Chapter I (Quality Management System)**

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2024-03-27  
Valid until 2027-11-27

Registration No. D1433000008  
Report No. P21-02044-295111

Stuttgart, 2024-03-27



Notified Body



## Devices:

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### Abutments

**Intended purpose:**

Intended for the fixation of overdentures or partial dentures supported in whole or in part by endosseous implants in the mandible or maxilla

Risk class: IIb

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### Retention Inserts and Denture Caps

Risk class: IIa

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### Insertion tools and insertion instruments

Risk class: IIa

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## Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

## The certificate is based on the previous certificates

- D1433000006 dated 2022-11-28 with the following changes:  
Supplemented by: Retention Inserts and Denture Caps
- D1433000007 dated 2023-05-12 with the following changes:  
Supplemented by: Insertion tools and insertion instruments