

EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000019555)

MEDEALIS GmbH

Im Steinböhl 9
69518 Abtsteinach
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils 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 consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-05-12	Registration No.	D1433000007
Valid until:	2027-11-27	Evaluation Report No.	P21-02044-266817

Stuttgart, 2023-05-12



Head of Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zfg.de
BS-MDR-098

Devices:

Product: 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

Product: Retention Inserts and Denture Caps

Risk class: IIa

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 certificate D1433000006 dated 28.11.2022 with the following changes:
Supplemented by: Retention Inserts and Denture Caps