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-000008124)

bredent GmbH & Co. KG

Weißenhorner Straße 2
89250 Senden
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:	2023-09-07	Registration No.	D1020200076
Valid until:	2027-10-01	Evaluation Report No.	P22-00146-227132

Stuttgart, 2023-09-07

Head of Notified Body

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

Devices:

Product: dental implants and accessories

Intended purpose: The product is intended to restore and/or correct the function, phonetic and aesthetics of existing teeth and/or lost teeth as part of a dental restoration.
It is an abutment or a blank for producing an individual abutment for custom-made dental products on implants.

Risk class: IIb

Product: dental prostheses

Risk class: IIa

Product: devices for prosthetic dentistry – others

Risk class: IIa

Product: devices for prosthetic dentistry – accessories

Risk class: IIa

Product: dental impression devices for prosthetic dentistry

Risk class: IIa

Product: resins and dental crowns

Risk class: IIa

Product: resins and dental crowns

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.