EU Quality Management System Certificate

We hereby certify the company

bredent GmbH & Co. KG
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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 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-12-20	Registration No.	D1020200078
Valid until	2027-10-01	Report No.	P23-01318-280461

Stuttgart, 2024-12-20

Notified Body

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

Devices:

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

Dental impression devices for prosthetic dentistry

Risk class: IIa

Resins and dental crowns

Risk class: IIa

Devices for prosthetic dentistry – others

Risk class: IIa

Dental restorative devices

Risk class: IIa

Devices for prosthetic dentistry – accessories

Risk class: IIa

Dentures

Risk class: IIa

Dentistry instruments - other

Risk class: IIa

Materials for the preparation of custom made devices - other

Risk class: IIa

Dentistry instruments - other

Risk class: I (reusable)

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

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

D1020200076 (2023-09-07)

with the following changes to D1020200076:
Supplemented by:
Dentures; risk class IIa
Dentistry instruments - other; risk class IIa
Materials for the preparation of custom made devices - other; risk class IIa
Dentistry instruments - other; risk class I (reusable)
and
Rewording of product group "Dental prostheses" to "Dental restorative devices"