# EU Quality Management System Certificate

We hereby certify the company

**bredent medical GmbH & Co. KG**
**Weißenhorner Straße 2**
**89250 Senden**
**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 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

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|---|---|---|---|
| Valid from | 2024-12-12 | Registration No. | D1146000055 |
| Valid until | 2027-10-01 | Report No. | P23-00466-319765 |

Stuttgart, 2024-12-12

Notified Body

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

## Devices:

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Dental Implants and accessories

Intended purpose: The product is intended to restore and/or correct the function, phonetics and aesthetics of existing teeth and/or lost teeth as part of a dental restoration.
These are dental titanium or zirconium implants for insertion into the jaw bone.

Risk class: IIb

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Devices for prosthetic dentistry - accessories and others

Risk class: IIa

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dental impression devices for prosthetic dentistry

Risk class: IIa

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Odontostomatology instruments - others

Risk class: IIa

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Odontostomatology instruments - others

Risk class: I (reusable)

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Dental implants and accessories

Intended purpose: The product is needed to manufacture dental restoration to restore and/or correct the function, phonetics and aesthetics of existing teeth and/or lost teeth. These are anchoring elements or blanks used to manufacture customised anchoring elements for custom-made dental implants.

Risk class: IIb

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Dental implants and accessories

Risk class: IIa

## 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

D1146000051 (2023-06-21)
D1146000054 (2024-08-05)

with the following changes to D1146000054:
Supplemented by the product: Dental implants and accessories with the intended purpose: The product is needed to manufacture dental restoration to restore and/or correct the function, phonetics and aesthetics of existing teeth and/or lost teeth. These are anchoring elements or blanks used to manufacture customised anchoring elements for custom-made dental implants. Risc class IIb and
supplemented by the product: Dental implants and accessories, Risc class IIa