

# EU Quality Management System Certificate

We hereby certify the company

**bredent medical GmbH & Co. KG**  
**Weißenhornstraße 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.

Valid from 2026-02-18  
Valid until 2027-10-01

Registration No. D1146000058  
Report No. P23-00400-262246

Stuttgart, 2026-02-18



Notified Body



## Devices:

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Dental implants and accessories – P010201

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

Risk class: IIb

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Odontostomatology instruments, reusable – other – L159099

Risk class: IIa

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Odontostomatology instruments, reusable – other – L159099

Risk class: I (reusable)

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Dental implants and accessories – P010201

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 healing abutments and anchoring elements used to fasten custom-made dental devices to implants.

Risk class: IIb

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Dental implants and accessories - P010201

Risk class: IIa

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Dental Instruments, single-use - Other - Q010599

Risk class: IIa

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#### Therapeutic Lasers - Z120615

Intended purpose: It is a hand-held therapeutic laser designed to transmit low-energy light onto the body surface and into natural openings in the body for wound care.  
The mini-laser is designed for use in low-level laser therapy to treat wounds, pain, inflammation and physiological diseases.

Risk class: IIb

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#### Therapeutic Lasers - Z120615

Intended purpose: It is a hand-held therapeutic laser intended to emit low-energy light.  
The laser is used in the mouth/jaw/face for antimicrobial application by means of photodynamics and for reducing inflammation, relieving pain and promoting wound healing through low-level laser therapy.

Risk class: IIb

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### 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)  
D1146000055 (2024-12-12)

with the following changes to D1146000055:

Supplemented by Therapeutic Lasers; Dental instruments, single-use - Other and applicable EMDN codes  
Restricted by: Devices for prosthetic dentistry – accessories and others and dental impression devices for prosthetic dentistry