

# EU Quality Management System Certificate

We hereby certify the company

**Ritter Implants GmbH & Co. KG**  
**Freiburger Straße 45**  
**88400 Biberach**  
**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 2024-03-21  
Valid until 2027-12-02

Registration No. D1500300003  
Report No. P22-00695-235441

Stuttgart, 2024-03-21



Notified Body



## Devices:

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Dental implants (QSI Ri-Quadro Spiral Implants, NL-QSI Ri-Quadro Spiral Implantate-Narrow Line, SB/LA Spiral Implants, SB/LA Spiral Implants-Narrow Line, iOs3/ Ora3/ iT3, Lamina/ iH/ QSI, Augmentat iH/ Lamina Augmentat/ Augmentat iV/ Artic Augmentat/ Augmentat iT/ Fortis Augmentat, Artic/ Ora/ iV, Fortis/ iT, i8)

**Intended purpose:**

Restoration of masticatory function to replace teeth in the edentulous or partially edentulous upper/lower jaw for implantation in the jawbone

Risk class: IIb

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Abutments (titanium, zirconium, transfer abutment systems, ball systems, clicq systems, multi-unit systems)

**Intended purpose:**

Restoration of masticatory function for the replacement of teeth as a connecting piece between implant and prosthetics in the upper/lower jaw for the attachment of removable or fixed dentures

Risk class: IIb

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Dental drills and surgical kits (Pilot drills, cortical drills, conical drills, parallel drills, motor insertion tool prosthetics, motor insertion tool implants)

Risk class: IIa

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Transfer accessories (transfer caps)

Risk class: IIa

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Screws (cover, abutment)

**Intended purpose:**

Cover screw to protect the implant during the healing phase; abutment screw is used to connect the implant and abutment in the maxilla/lower jaw for temporary or permanent attachment of prosthetics to implants

Risk class: IIb

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Healing accessories (healing caps)

Intended purpose: Esthetic representation of the natural gingival line in the upper/lower jaw for shaping the soft tissue portion

Risk class: IIb

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Abutments (temporary abutments, caps, scanbodies)

Risk class: IIa

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Milling blank

Intended purpose:  
Blank to produce abutments in the CAD CAM process

Risk class: IIb

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Ti base

Intended purpose:  
Adhesive base for the fabrication of abutments in the CAD/CAM process

Risk class: IIb

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## 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.