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-000009117)

MEDENTiKA GmbH

Hammweg 8-10
76549 Hügelsheim
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 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-06-12	Registration No.	D1278600022
Valid until:	2027-07-28	Evaluation Report No.	P22-01722-252662

Stuttgart, 2023-06-12

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
MICROCONE Implants; QUATTROCONE Implants; MINICONE Implants; PROCONE Implants

Intended purpose:
Dental implants are used to anchor dentures in the jawbone. They support both single tooth restorations as well as conditionally removable or fixed as well as removable bridge constructions and dentures.

Risk class: IIb

Product:
Abutments and abutment components
CADCAM abutments; Castable abutments; SRBB abutments; Temporary abutments; Locator abutments; Standard and solid abutments

Intended purpose:
Used to manufacture prosthetic components on implants. The abutments are used in combination with crowns and bridges to reconstruct function and aesthetics.

Risk class: IIb

Product:
Gingiva formers

Intended purpose:
The Gingiva former is used to shape the gingiva around the implant during the healing process (open healing) or after the implant has healed (closed healing).

Risk class: IIb

Product:
Closure screws

Intended purpose:
The closure screws are used to close the implant during healing, to prevent colonisation with biological tissues or accumulation of body fluids (closed healing).

Risk class: IIb

Product:
Drills and drill stops

Risk class: IIa

Product:
Instruments and accessories
Placement instruments; deph gauges; drill aids

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.