EU Quality Management System Certificate

We hereby certify the company

Medigma Biomedical GmbH
Siemensstraße 10
78564 Wehingen
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	2023-11-14	Registration No.	D1418500009
Valid until	2028-11-13	Report No.	P22-01484-248168

Stuttgart, 2023-11-14

Notified Body

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

Devices:

Dental Implants:
FixTite™-S dental implants
Mars™ dental implants
Fix-a-Dent™ dental implants
Fix1™ dental implants
Fix Konisch™ dental implants
Grand Konisch™ dental implants

Intended purpose: Medigma's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Risk class: IIb

Abutments (non-sterile):
Healing Abutments
Cement Retained Abutments
Screw Retained Abutments
Cement or Screw Retained Abutments (UCLA Abutments)
Prosthetic Components for CAD/CAM (Multi-Unit Cementing Cone, Ti base, Ti blank)
Overdenture Attachments (Ball Attachment)
Abutment Screws
Implant's Cover Screws

Intended purpose: Medigma's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

Risk class: IIb

Freehand Surgery Drills

Risk class: IIa

Freehand Surgery Handpiece Connected Tools

Risk class: IIa

Guided Surgery Drills

Risk class: IIa

Guided Surgery Handpiece Connected Tools

Risk class: IIa

Anchorage Screws

Risk class: IIa

Osteotomes

Risk class: I (reusable)

Guided Surgery Tissue Punches

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.