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Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

ALTATEC GmbH
Maybachstraße 5
71299 Wimsheim
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	2026-06-25	Registration No.	D1063900002
Valid until	2031-06-24	Report No.	P25-00874-341015

Stuttgart, 2026-05-20

Notified Body

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

Devices:

P010201 - Dental Implants and Accessories

Intended purpose: CAM blanks are intended for fabricating individualized abutments for the functional and/or esthetic oral rehabilitation of partially or fully edentulous patients in combination with endosseous implants in the maxilla and/or mandible; In addition, titanium CAM blanks are intended for fabricating individualized healing caps for the conditioning of the soft tissue during the healing phase in combination with endosseous implants in the maxilla and/or mandible

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Abutment screws are intended for the fixation of abutments and other suitable components onto dental implants

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Abutments are intended for the functional and/or esthetic oral rehabilitation of partially or fully edentulous patients in combination with endosseous implants in the maxilla and/or mandible

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Cover screws / cover caps are intended for the covering of the implant during submerged healing in combination with endosseous implants in the maxilla and/or mandible

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Dental implants are intended for the functional and/or esthetic oral rehabilitation of partially or fully edentulous patients as endosseous implants in the maxilla and/or mandible

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Healing caps are intended for the conditioning of the soft tissue in combination with endosseous implants in the maxilla and/or mandible

Risk class: IIb

P010201 - Dental Implants and Accessories

Intended purpose: Temporary abutments are intended for the transitional oral rehabilitation of partially or fully edentulous patients in combination with endosseous implants in the maxilla and/or mandible

Risk class: IIb

Instruments for Dental Treatment Units

Risk class: IIa

Dental Implants and Accessories

Risk class: IIa

Odontostomatology Osteotomes, reusable

Risk class: I (reusable)

Instruments for Dental Treatment Units

Risk class: I (sterile)

Notes:

For class I devices placed on the market in sterile condition the involvement of mdc is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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.