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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 076870 0020 Rev. 01

Manufacturer:

ALTATEC GmbH
Maybachstr. 5
71299 Wimsheim
GERMANY

SRN Manufacturer - DE-MF-000006230

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 076870 0020 Rev. 01

Report No.: 713253407

Preceding Certificate No.: G10 076870 0020 Rev. 00

Valid from: 2023-08-10
Valid until: 2026-06-24

Date of Initial Issuance: 2021-06-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-08-10

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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(Class IIa and Class IIb Devices)

No. G10 076870 0020 Rev. 01

Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Abutment screws are intended for the fixation of abutments and other suitable components onto dental implants.

Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Abutments & Titanium bases / bonding bases 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.

Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Ball abutments are intended for the functional and/or esthetic oral rehabilitation of fully edentulous patients in combination with endosseous implants in the maxilla and/or mandible.

Classification:	Class IIb
Device Group:	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.

Classification:	Class IIb
Device Group:	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.

Classification:	Class IIb
Device Group:	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.

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(Class IIa and Class IIb Devices)

No. G10 076870 0020 Rev. 01

Classification:	Class IIb
Device Group:	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.

Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Temporary abutments are intended for the transitional oral rehabilitation (maximum of 180 days) of partially or fully edentulous patients in combination with endosseous implants in the maxilla and/or mandible.

Classification:	Class IIb
Device Group:	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.

Classification:	Class IIa
Device Group:	Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2021-06-25	713180515	-
01	2023-08-10	713253407	Supplemented: Device(s)/group of device(s) added

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