



America

CERTIFICATE

No. QS6 076870 0019 Rev. 01

Certificate Holder: **ALTATEC GmbH**
Maybachstr. 5
71299 Wimsheim
GERMANY

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Dental Implants, Abutments, Drills, Instruments and Equipment Supporting Impression Taking and Bonding for Dental Applications**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, MHLW / PMDA.**
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002956**

Effective Date: **2022-10-31**

Expiry Date: **2025-10-30**

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Date of Issue: 2022-11-17

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

ALTATEC GmbH
Maybachstr. 5, 71299 Wimsheim, GERMANY

Camlog Biotechnologies GmbH
Margarethenstraße 38, 4053 Basel, SWITZERLAND

ALTATEC GmbH
Paul Ehrlich Str. 15, 72076 Tübingen, GERMANY

CAMLOG Management GmbH
Maybachstr. 5, 71299 Wimsheim, GERMANY

CAMLOG Vertrieb GmbH
Maybachstraße 5, 71299 Wimsheim, GERMANY

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Facility Scopes:

ALTATEC GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Production and Distribution of Dental Implants, Abutments, Drills, Instruments and Equipment Supporting Impression Taking and Bonding for Dental Applications
REPs Facility ID: F002956

Camlog Biotechnologies GmbH

Margarethenstraße 38, 4053 Basel, SWITZERLAND

Design and Development of Dental Implants, Abutments, Drills, Instruments and Equipment Supporting Impression Taking and Bonding for Dental Applications
REPs Facility ID: F004641

ALTATEC GmbH

Paul Ehrlich Str. 15, 72076 Tübingen, GERMANY

Surface Treatment of Dental Implants, Abutments and Equipment Supporting Impression Taking and Bonding for Dental Applications
REPs Facility ID: F002956

CAMLOG Management GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Resource Management
REPs Facility ID: F002956

CAMLOG Vertrieb GmbH

Maybachstraße 5, 71299 Wimsheim, GERMANY

Distribution of Dental Implants, Abutments, Drills, Instruments and Equipment Supporting Impression Taking and Bonding for Dental Applications
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