



America

CERTIFICATE

No. QS6 076870 0019 Rev. 00

Certificate Holder:

ALTATEC GmbH
Maybachstr. 5
71299 Wimsheim
GERMANY

Certification Mark:



Scope of Certificate:

**Design, Development, Manufacturing and Distribution
of Dental Alloys, Dental Implants and Appendant
Abutments, Drills, Instruments and Medical Devices
Supporting Impression Taking and Bonding**

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 <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

32-201-8193

Effective Date:

2019-12-18

Expiry Date:

2022-12-17

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Date of Issue: 2020-02-26

(Tina Israel)
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
- 21 CFR Part 821

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

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Facility Scopes:

ALTATEC GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Manufacturing and Distribution of Dental Alloys, Dental Implants and Appendant Abutments, Drills and Instruments
DUNS No: 32-201-8193

Camlog Biotechnologies AG

Margarethenstraße 38, 4053 Basel, SWITZERLAND

Design and Development of Dental Alloys, Dental Implants and Appendant Abutments, Drills and Instruments
DUNS No: 48-217-4864

ALTATEC GmbH

Paul Ehrlich Str. 15, 72076 Tübingen, GERMANY

Surface Treatment of Implants and Appendant Abutments, Drills and Instruments
DUNS No: 48-217-4864

CAMLOG Management GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Administration
DUNS No: 48-217-4864



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Manager, US Certification Body,
Medical and Health Services