



America

CERTIFICATE

No. QS6 076870 0019 Rev. 04

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

Certification Mark:



Scope of Certificate: **Design, Development, Production and Distribution of Sterile and Non-Sterile 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, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_076870_0019_Rev.04

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

REPs Facility ID: **F002956**
Report No.: **713330438**
Effective Date: **2024-09-16**
Expiry Date: **2027-09-15**

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Date of Issue: 2024-07-23

(Renee Walker)
Director, US Certification Body, MHS

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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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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

CAMLOG Management GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

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Facility Scopes:

ALTATEC GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

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

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Camlog Biotechnologies GmbH

Margarethenstraße 38, 4053 Basel, SWITZERLAND

Design and Development of Sterile and Non-Sterile Dental Implants, Abutments, Drills, Instruments and Equipment Supporting Impression Taking and Bonding for Dental Applications

REPs Facility ID: F004641

CAMLOG Management GmbH

Maybachstr. 5, 71299 Wimsheim, GERMANY

Resource Management

REPs Facility ID: F002956

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