



America

CERTIFICATE

No. QS6 090341 0016 Rev. 00

Certificate Holder: **Candulor AG**
Boulevard Lilienthal 8
8152 Glattpark (Opfikon)
SWITZERLAND

Certification Mark:



Scope of Certificate: **Manufacturing and Distribution of Resin and Ceramics Teeth, Denture Base Materials, Dental Instruments for Removable Prosthetics**

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

Regulatory Authority(ies): **Australia TGA, Health Canada, 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. 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.

DUNS No: **48-046-7422**

Effective Date: **2021-03-24**

Expiry Date: **2024-03-12**

Page 1 of 2

Date of Issue: 2021-03-24

(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 4 – Production Quality Assurance Procedure

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

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

Facility(ies): Candulor AG
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 SWITZERLAND

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Page 2 of 2
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