ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 090341 0016 Rev. 01

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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 090341 0016 Rev. 01
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001198**
Report No.: **713296223**
Effective Date: **2024-03-13**
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Date of Issue: 2024-02-26

(Renee Walker)

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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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