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America

CERTIFICATE

No. QS6 18 03 90341 014

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

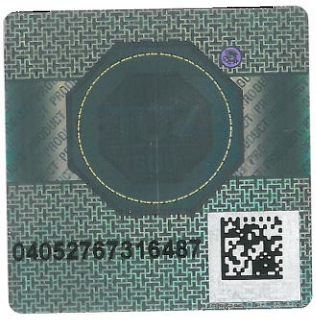
Regulatory Authority: TGA, Health Canada, FDA.
See attached for listing of specific regulatory requirements.

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
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

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

DUNS No:	**48-046-7422**
Effective Date:	**2018-03-23**
Expiry Date:	**2021-03-12**

Manuel Bradaric
MHS Certification Manager



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Audit/Certification Criteria

Australia

- **Therapeutic Goods (Medical Devices) Regulations 2002**
- **Schedule 3, Part 4**

Canada

- **Medical Device Regulations SOR/98-282, Part 1**

United States

- **21 CFR Part 803**
- **21 CFR Part 806**
- **21 CFR Part 807**
- **21 CFR Part 820**
- **21 CFR Part 821**

Effective Date:	**2018-03-23**
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Manuel Bradaric
MHS Certification Manager

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com

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