



America

# CERTIFICATE

No. QS6 055249 0014 Rev. 00

**Certificate Holder:** **SAREMCO DENTAL AG**  
Gewerbstrasse 4  
9445 Rebstein  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production and Distribution of Dental Filling Materials and Fissure Sealants, Adhesives for Dental Filling Materials, Cements for Dental Restoration, Etching Gels, Dental Resins for 3D-Printing, Luting Materials for Orthodontic Appliances**

**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 055249 0014 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_055249_0014_Rev.00)

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

**REPs Facility ID:** **F007112**  
**Report No.:** **713282697**  
**Effective Date:** **2024-03-26**  
**Expiry Date:** **2027-03-25**

Page 1 of 2

Date of Issue: 2024-04-11

( 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

**Canada**

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

**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):**

**SAREMCO DENTAL AG**

Gewerbestrasse 4, 9445 Rebstein, SWITZERLAND

**Facility Scopes:**

Design, Development, Production and Distribution of Dental Filling Materials and Fissure Sealants, Adhesives for Dental Filling Materials, Cements for Dental Restoration, Etching Gels, Dental Resins for 3D-Printing, Luting Materials for Orthodontic Appliances  
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Page 2 of 2

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