



America

CERTIFICATE

No. QS6 115516 0003 Rev. 00

Certificate Holder:

DSSM AG
Im alten Riet 9
9494 Schaan
LIECHTENSTEIN

Certification Mark:



Scope of Certificate:

**Design and Development, Production and Distribution
of Dental Products for Prophylaxis, Restoration
and Prosthetics**

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 115516 0003 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_115516_0003_Rev.00)

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

REPs Facility ID:

F007110

Report No.:

713308370

Effective Date:

2024-02-05

Expiry Date:

2027-02-04

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Date of Issue: 2024-02-20

(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, Part 1

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):

DSSM AG

Im alten Riet 9, 9494 Schaan, LIECHTENSTEIN

DSSM GmbH

Ludwig-Kick-Straße 2, 88131 Lindau, GERMANY

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Facility Scopes:

DSSM AG

Im alten Riet 9, 9494, Schaan, LIECHTENSTEIN

Design and Development, Production and Distribution of Dental Products for Prophylaxis, Restoration and Prosthetics

REPs Facility ID: F007110

DSSM GmbH

Ludwig-Kick-Straße 2, 88131, Lindau, GERMANY

The Provision of Sales, Marketing and Distribution of Dental Products for Prophylaxis, Restoration and Prosthetics

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