



America

CERTIFICATE

No. QS6 082649 0003 Rev. 00

Certificate Holder: DENTSPLY Implants Manufacturing GmbH
Rodenbacher Chaussee 4
63457 Hanau
GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Products for Dental Implantology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No: 34-403-8836

Effective Date: 2019-05-10

Expiry Date: 2022-01-28

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Date of Issue: 2019-05-16

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

DENTSPLY Implants Manufacturing GmbH
Rodenbacher Chaussee 4, 63457 Hanau, GERMANY

DENTSPLY IH AB
Aminogatan 1, PO Box 14, 43121 Mölndal, SWEDEN

DENTSPLY IH Inc.
590 Lincoln Street, Waltham MA 02451, USA

Sirona Dental Systems GmbH
Fabrikstr. 31, 64625 Bensheim, GERMANY

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Date of Issue: 2019-05-16



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CERTIFICATE

No. QS6 082649 0003 Rev. 00

Facility Scopes:

DENTSPLY Implants Manufacturing GmbH

Rodenbacher Chaussee 4, 63457 Hanau, GERMANY

Production, Surface Treatment, Final Inspection, Cleaning and Packaging of Products for Dental Implantology

DUNS No: 34-403-8836

DENTSPLY IH AB

Aminogatan 1, PO Box 14, 43121 Mölndal, SWEDEN

Design and Development, Production, Surface Treatment, Final Inspection, Cleaning, Packaging of Products for Dental Implantology; Production, Surface Treatment, Final Inspection, Cleaning, Packaging and Distribution of Custom-Made / Patient Specific Dental Abutments

DUNS No: 35-405-9073

DENTSPLY IH Inc.

590 Lincoln Street, Waltham MA 02451, USA

Design and Development, Production, Surface Treatment, Final Inspection, Cleaning, Packaging and Distribution of Scanning Aids and Custom-Made / Patient Specific Dental Abutments; Production, Surface Treatment, Final Inspection, Cleaning, Packaging and Distribution of Custom-Made / Patient Specific Surgical Guides, Dental Suprastructures, Dental Crowns and Bridges; Distribution of Products for Dental Implantology

DUNS No: 84-733-7201

Sirona Dental Systems GmbH

Fabrikstr. 31, 64625 Bensheim, GERMANY

Design and Development of Products for Dental Implantology

DUNS No: 34-030-6351



(Arie Henkin)
Manager, Certification Body MHS

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