



America

CERTIFICATE

No. QS6 082652 0007 Rev. 00

Certificate Holder: DENTSPLY IH Inc.
590 Lincoln Street
Waltham MA 02451
USA

Certification Mark: 

Scope of Certificate: 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

Standard(s): ISO 13485:2016

Regulatory Authority(ies): 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. 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: 84-733-7201

Effective Date: 2019-05-29

Expiry Date: 2022-01-28

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(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

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

Facility(ies):

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