




America

CERTIFICATE

No. QS6 031247 0085 Rev. 00

Certificate Holder: Sirona Dental Systems GmbH
Fabrikstr. 31
64625 Bensheim
GERMANY

Certification Mark: 

Scope of Certificate: See Page 2 for Overall Scope Statement.

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: 34-030-6351

Effective Date: 2019-03-04

Expiry Date: 2022-03-03

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Date of Issue: 2019-03-15

(Arie Henkin)
Manager, Certification Body MHS

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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

Overall Scope Statement:

Design and Development, Production and Distribution of Imaging Systems for Diagnosis for the area of Otolaryngology; Design, Development, Production and Distribution of the Dental Products for Therapy and Diagnosis Dental Treatment Units including the following Components: Electrical and Air Driven Dental Instruments: Handpieces and Angle Pieces, Turbines, Electrical and Air Driven Motors, Water and Air Spray Instruments, High Frequency Surgery, Scalers, UV-Light for Hardening of Synthetic Fillings, Cleaning-Disinfection-and Sterilizers Devices, Dental Laser Devices and their Sterile Disposables, CAD/CAM-Devices for Restoration, Laboratory Devices, Dental Alloys/Dental Materials; Distribution of Abutments and Abutments Screws

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Facility(ies):

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