



America

CERTIFICATE

No. QS6 019859 0026 Rev. 01

Certificate Holder:



NTI - Kahla GmbH
Rotary Dental Instruments
 Im Camisch 3
 07768 Kahla
 GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Rotary Dental and Podiatric Instruments, Parapulpal and Pulpal Restoration Pins for the Dental Field, Instruments for use in Dental Laboratories

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 www.tuvsud.com/ps-cert

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

REPs Facility ID:

F001712

Effective Date:

2021-12-30

Expiry Date:

2024-11-15

Page 1 of 2

Date of Issue: 2022-01-10

(Michael Ogunleye)
 Manager, US Certification Body,
 Medical and Health Services

CERTIFICATE

No. QS6 019859 0026 Rev. 01

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

Canada

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

Japan

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

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

NTI - Kahla GmbH Rotary Dental Instruments
 Im Camisch 3, 07768 Kahla, GERMANY

Facility Scopes:

Design and Development, Production and Distribution of Rotary Dental and Podiatric Instruments, Parapulpal and Pulpal Restoration Pins for the Dental Field, Instruments for use in Dental Laboratories
 REPs Facility ID: F001712

Page 2 of 2

Date of Issue: 2022-01-10



(Michael Ogunleye)
 Manager, US Certification Body,
 Medical and Health Services