

Certificate

Certificate No.: MD 282752 3251262-90

Manufacturer: **Gebr. Brasseler GmbH & Co. KG**
Trophagener Weg 25
32657 Lemgo
Germany

D-U-N-S No.: 31-740-9001

Certification criteria ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure and Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)
United States 21 CFR 820, 21 CFR 821, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 21208078 018
Issue Date: 2018-11-29
Effective Date: 2018-11-29
Expiry Date: 2021-10-18



Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

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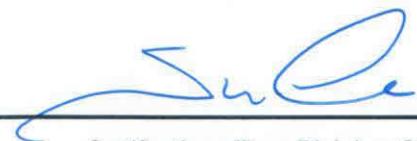
Scope: Design and development, manufacture and distribution of Rotary, oscillating and manually driven instruments for dentistry; Rotary instruments and saw blades for orthopedics, dermatology, surgery and ophthalmology; Posts, screws and prefabricated elements as well as auxiliary parts for the restoration of teeth; Composite systems for root post cementation and core build-up; Instruments for podiatry; Dental hand pieces and contra-angles; Rotary and manually driven endodontic instruments; Filling material for root canals and paper points for drying the root canal; Pins and screws for use in orthopedics; Sterilization containers and bur blocks.

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