Certificate

Certificate No.:	MD 1090723-40
Manufacturer:	**Gebr. Brasseler GmbH & Co. KG** Trophagener Weg 25 32657 Lemgo Germany
REPs Facility ID:	F001087
Certification criteria:	ISO 13485:2016 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 Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 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.:	1090723-230
Issue Date:	2021-10-13
Effective Date:	2021-10-19
Expiry Date:	2024-10-18

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105088010?locale=en or calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Certificate

Certificate No.: MD 1090723-40

Manufacturer: **Gebr. Brasseler GmbH & Co. KG**

Trophagener Weg 25
32657 Lemgo
Germany

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; Pins and screws for use in orthopedics; Sterilization containers and bur blocks.

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