

# Certificate

Certificate No.: MD 1470094-1-1

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. 665/2022, RDC ANVISA n. 551/2021,  
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

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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.: 1170869-690  
Issue Date: 2024-10-19  
Effective Date: 2024-10-19  
Expiry Date: 2027-10-18



*Daniela Wiedemuth*

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>  
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,
- Pins and screws for use in orthopedics,
- Sterilization containers and bur blocks.

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