

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1470094-1

Certificate Holder: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Germany

Scope: Design and development, manufacture and distribution of non-active medical devices

Products included:

- Rotary and oscillating 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,
- Instruments for podiatry,
- Pins and screws for use in orthopedics,
- Rotary endodontic instruments,
- Dental hand pieces and contra-angles,
- Sterilization containers and bur blocks,
- Manual instruments and tools for use in dentistry.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1170869-100

Effective date: 2024-10-19

Expiry date: 2027-10-18

Issue date: 2024-10-19

Replaces certificate SX 1470094-1 issued 2021-10-13.

Daniela Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>