

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1470094-1

Organization: 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.

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