

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture and distribution
of non-active medical devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-01-20
Certificate Registration No.: SX 60143837 0001
An audit was performed. Report No.: 21208078 025
This Certificate is valid until: 2023-01-19

Certification Body



Date 2019-12-18



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143837 0001
Report No.: 21208078 025

Organization: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Scope:

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
- Agents for the cleaning and disinfection of medical devices
- Pins and screws for use in orthopedics

Certification Body



Date: 2020-01-20



K. Schick
Dipl.-Ing. (FH) K. Schick

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

Registration No.: SX 60143837 0001
Report No.: 21208078 025

Organization: Gebr. Brasseler GmbH & Co. KG
Trophagener Weg 25
32657 Lemgo
Deutschland

Scope:

Products included:

- Rotary endodontic instruments
- Filling material for root canals and paper points for drying the root canal
- Dental hand pieces and contra-angles
- Sterilization containers and bur blocks
- Manual instruments and tools for use in dentistry
- Elastomeric elements

Certification Body



Date: 2020-01-20

K. Schick
Dipl.-Ing. (FH) K. Schick

