

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60135991 0001

Report No.: 21208078 021

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

Products: Non-active medical devices

(see attachment for products included)

Replaces Approval, Registration-No.: HD 60091372 0001

Expiry Date: 2024-01-19

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-01-20

Date: 2019-01-17

Notified Body


Dr. K. Kluge



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60135991 0001
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Manufacturer: Gebr. Brasseler GmbH & Co. KG
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32657 Lemgo
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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
- Composite systems for root post cementation and core build-up
- Instruments for podiatry
- Agents for the cleaning and disinfection of medical devices
- Pins and screws for use in orthopedics
- Rotary endodontic instruments
- Filling material for root canals and paper points for drying the root canal
- Dental hand pieces and contra-angles

Date: 2019-01-17

Notified Body

Dr. K. Kluge
Dr. K. Kluge



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
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For the following devices the scope covers only
the aspects of the manufacture concerned with
the securing and maintaining sterile conditions:

- Manual instruments and tools for use in dentistry

Date: 2019-01-17

Notified Body

Dr. K. Kluge
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