

**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  
**Report No.:** 21208078 023

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

**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
- Rotary endodontic instruments
- Filling material for root canals and paper points for drying the root canal
- Dental hand pieces and contra-angles
- Manual instruments and tools for use in dentistry

**Date:** 2019-02-11

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**



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

Doc. 2/2, Rev. 1

**Attachment to  
Certificate**

**Registration No.:** HD 60135991 0001  
**Report No.:** 21208078 023

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

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:** 2019-02-11

**Notified Body**

*Dr. K. Kluge*  
**Dr. K. Kluge**

