



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

Registration No.: HD 60091372 0001

Report No.: 21208078 001

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 60028332 0001

Expiry Date: 2019-01-19

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: 2014-01-20

Date: 2014-01-20

Notified Body

Dipl.-Ing. D. Meier



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

Doc. 1/2, Rev. 1

**Attachment to
Certificate**

Registration No.: HD 60091372 0001
Report No.: 21208078 004

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
- Dental implants
- 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
- Elastomeric elements

Date: 2015-10-02

Notified Body

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60091372 0001
Report No.: 21208078 004

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: 2015-10-02

Notified Body

Dipl.-Ing. D. Meier

