

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

Registration No.: HD 60121462 0001

Report No.: 21240670 014

Manufacturer: Kulzer GmbH
Leipziger Str. 2
63450 Hanau
Deutschland

Products: Design/Development and Manufacture of dental products
(see attachment for products and sites included)
Replaces Approval, Registration No.: HD 60108063 0001

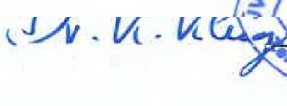
Expiry Date: 2021-02-03

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: 2017-07-10

Date: 2017-07-10

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

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60121462 0001
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Manufacturer: Kulzer GmbH
Leipziger Str. 2
63450 Hanau
Deutschland

Products included:

- Dental material, pit/fissure sealing, polymer based
- Dental material, filling/ restorative, polymer-based
- Burnisher, dental
- Dental implant, bone reconstruction
- Cement, dental, polycarboxylate
- Cement, dental, zinc phosphate
- Cement, dental, polymer based
- Bur, dental, diamond
- Dental etching liquid/-gel
- Dental material, denture base, polymer based
- Crown/bridge material
- Adhesives, dentine
- Needles, dental

Notified Body

Date: 2017-07-10

Dr. K. Kluge



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
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Registration No.: HD 60121462 0001
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Manufacturer: Kulzer GmbH
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63450 Hanau
Deutschland

Products included:

- Crown/bridge, temporary
- Dental ceramic
- Dental alloy and -solders, noble
- Dental alloy and -solders, non-noble
- Attachments
- Electro plating baths for dental applications
- Precious metal pastes for dental applications
- Abutment, dental
- 3D printing material for dental splints

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60121462 0001
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Manufacturer: Kulzer GmbH
Leipziger Str. 2
63450 Hanau
Deutschland

Sites included:

- Kulzer GmbH
Quarzstraße 8, 63450 Hanau, Germany

Activities: Design/Development and manufacture of dental products, CAD/CAM and Selective Laser Melting Process of precious and non-precious metal materials, ceramics and PMMA, dental attachments

- Kulzer Austria GmbH
Nordbahnstr. 36, 1020 Wien, Austria

Activity: Manufacture of precious metal dental materials

- Kulzer GmbH
Philipp-Reis-Str. 8/13, 61273 Wehrheim, Germany

Activities: Design/Development and manufacture of dental materials