

**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  
**Report No.:** 21240670 014

**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  
Certificate**

**Registration No.:** HD 60121462 0001  
**Report No.:** 21240670 014

**Manufacturer:** Kulzer GmbH  
Leipziger Str. 2  
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

**Date:** 2017-07-10

**Notified Body**

  
**Dr. K. Kluge**



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

**Attachment to  
Certificate**

**Registration No.:** HD 60121462 0001  
**Report No.:** 21240670 014

**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

**Notified Body**

**Date:** 2017-07-10

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

