

**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*  
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 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

**Date:** 2017-07-10

**Notified Body**

*Dr. K. Kluge*  
**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

**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*  
**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

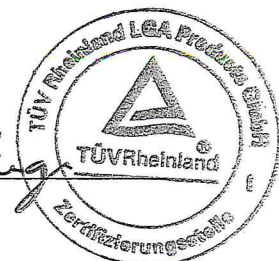
- Kulzer GmbH  
Philipp-Reis-Str. 8/13, 61273 Wehrheim, Germany

Activities: Design/Development and manufacture of dental materials

**Date:** 2017-07-10

**Notified Body**

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





## KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse der Firma /  
Name and address of the company

**Kulzer GmbH**  
Leipziger Str. 2  
63450 Hanau  
Deutschland / Germany

**Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that**

Die Medizinprodukte der Klasse IIa  
The medical devices class IIa

**Dental periodontic cement**

Carboxylate Cement

**Light-cured dental restorative composite resin**

Charisma Classic  
Charisma Diamond  
Charisma Flow  
Charisma Opal  
Charisma Opal Flow  
Charisma Smart  
Charisma Topaz  
Flow Line  
Durafill VS  
Venus Bulk Fill

**Selfcuring resin for temporary crown and bridges**

Dentalon Plus

**Temporary crown and bridge resin**

PreVision Temp

**Adhesive, dentine**

Gluma 2Bond  
Gluma Bond Universal/Gluma Ceramic Primer  
Gluma Self Etch

**Dental bonding agent**

Gluma Desensitizer

**Dental etching**

Gluma Etch

**Dental periodontic cement**

Phosphate Cement

**Cement, dental**

PreVision CEM

**Steril single-use dental needles**

SeleKT  
Sopira Carpule Needles

**Dental occlusal splint**

dima Print Ortho



**Resin artificial teeth**

Opdodent  
Optognath  
Optostar  
Artic  
Delara  
Mondial  
Premium

**Denture base resin**

Meliodont HC, powder & liquid  
Meliodont Orthodontic, powder & liquid  
Meliodont RR, powder & liquid  
Palabond  
Pala cre-active  
Paladent 20, powder & liquid  
Paladent RR, powder & liquid  
Paladon 65, powder & liquid  
Paladur, powder & liquid  
Palapress vario, powder & liquid  
Palapress, powder & liquid  
Palaseal  
Palavit 55 VS, powder & liquid  
PalaXpress, powder & liquid

**Dental crown resin**

Signum ceramic bond  
Signum ceramis  
Signum composite/composite flow/matrix  
Signum connector  
Signum cre-active  
Signum liquid  
Signum metal bond  
Signum opaque F  
Signum zirconia bond

**Dental Ceramics**

HeraCeram  
HeraCeram Saphir  
HeraCeram Zirkonia  
HeraCeram Zirkonia 750  
dima Mill Zirkonia  
dima Mill Zirkonia ML

**Non-precious metal alloys**

Heraenium EH  
Heraenium CE  
Heraenium NF  
Heraenium P  
Heraenium Laser  
Heraenium NA  
Heraenium Sun  
Heraenium Pw  
Heraenium S  
dima Mill CoCr solid



Die Medizinprodukte der Klasse I  
*The medical devices of class I*

**Impression Material, dental, silicon rubber**

Activator Universal plus  
Optosil Comfort/ P Plus  
Variotime  
Xantopren H/M/L/VL  
OXASIL

**Impression material, dental, alginate**

Alginoplast  
Xantalgin

**Dynamix Speed – n.a.**

**Dental Syringe, anaesthesia**

Sopira Citoject

**Bite registration device, bite rim**

Variotime Bite

**Surgical guide, non-sterile**

dima Print Guide

**Dental impression tray material**

dima Print Impression blue  
Palavit L, powder & liquid

allen Anforderungen der Richtlinie 93/42/EWG entspricht, die anwendbar sind /  
*meets all the provisions of the Directive 93/42/EEC which apply to it.*

Hanau, 13.6.2019

Marc Berendes  
Chief Executive Officer (CEO)  
Kulzer GmbH

Ort, Datum / Place, date

Name und Funktion / Name and function

Diese Konformitätserklärung ist gültig in Verbindung mit den Freigabe-Dokumenten für die jeweilige Charge der produzierten Medizinprodukte / *This statement of conformity is valid in connection with the release documents for the respective batch of produced devices.*

Urkundenrolle-Nr.: 137 / 2019 P

Hiermit beglaubige ich die heute vor mir anerkannte Unterschrift von

Herrn **Marc Berendes**, geb. am 19.06.1970,  
dienstansässig Leipziger Str. 2, 63450 Hanau.

Herr **Marc Berendes** ist dem Notar von Person bekannt.

Herr **Marc Berendes** handelt als Geschäftsführer für die Firma Kulzer GmbH mit Sitz in Hanau.

Gleichzeitig bescheinige ich aufgrund meiner heutigen Einsichtnahme in das elektronische Handelsregister des Amtsgerichts Hanau zu HRB 91228, dass Herr **Marc Berendes** als Geschäftsführer der Firma Kulzer GmbH einzelvertretungsberechtigt ist mit der Befugnis, im Namen der Gesellschaft mit sich im eigenen Namen oder als Vertreter eines Dritten Rechtsgeschäfte abzuschließen.

Gleichzeitig halte ich fest, dass die Frage nach einer Vorbefassung im Sinne von § 3 Abs. 1 Nr. 7 BeurkG verneint wurde.

Hanau, den 13. Juni 2019  
(Leipziger Straße 2)

  
Dr. Frederik Putzo  
Notar



Document Register No.: 137 / 2019 P

Herewith certify the signature acknowledged in front of me of

Mr. **Marc Berendes**, born on June 19<sup>th</sup>, 1976,  
with registered office at Leipziger Str. 2, 63450 Hanau.

Mr. **Marc Berendes** is personally known by the notary.

Mr. **Marc Berendes** is acting as Managing Director to represent the company Kulzer GmbH with registered office at Hanau.

On the basis of today's inspection of the electronic commercial register by the local court Hanau under HRB 91228, I herewith confirm, that Mr. **Marc Berendes** is entitled to represent the company Kulzer GmbH at Hanau. Mr. **Marc Berendes** as Managing Director is authorized, in the name of the society with itself in the own name or as representatives third legal transactions to make.

I do establish at the same time, that the interested parties denied the question of a prior involvement according to § 3 Sec. No. 7 BeurkG.

Hanau, June 13<sup>rd</sup>, 2019  
(Leipziger Straße 2)

  
Dr. Frederik Putzo  
notary

