

Certificate

Certificate No.: MD 1198082-1-1

Manufacturer: **Kulzer GmbH**
Leipziger Str. 2
63450 Hanau
Germany

REPs Facility ID: F001084

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,
PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D,

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TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1172551-691

Issue Date: 2024-12-17

Effective Date: 2024-12-19

Expiry Date: 2027-12-18



Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

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or calling 1-888-743-4652.

Certificate

Certificate No.: MD 1198082-1-1

Manufacturer: **Kulzer GmbH**
Leipziger Str. 2
63450 Hanau
Germany

Scope: Design and Development, Manufacture and Distribution of Dental appliance fabrication material, ceramic; Dental appliance fabrication material, resin; Dental casting noble alloy; Bite registration rim; Temporary dental crown/bridge; Dentine bonding agent/set; Dental casting non-noble alloy; Dental composite resin; Dental etching solution; Dental impression material adhesive; Dental prosthesis veneer resin; Silicone dental impression material; Resin artificial teeth; Dental prosthesis priming agent; Dental coating, tooth-desensitizing, professional; Dental composite resin kit



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Certificate

Certificate No.: MD 1198082-1-1
 Manufacturer: **Kulzer GmbH**
 Leipziger Str. 2
 63450 Hanau
 Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/01	Kulzer GmbH Leipziger Str. 2 63450 Hanau Germany REPs Facility ID: F001084	Design and Development, Distribution and Administration of Dental appliance fabrication material, ceramic; Dental appliance fabrication material, resin; Dental casting noble alloy; Bite registration rim; Temporary dental crown/bridge; Dentine bonding agent/set; Dental casting non-noble alloy; Dental composite resin; Dental etching solution; Dental impression material adhesive; Dental prosthesis veneer resin; Silicone dental impression material; Resin artificial teeth; Dental prosthesis priming agent; Dental coating, tooth-desensitizing, professional; Dental composite resin kit
/02	Kulzer GmbH Philip Reis Str. 8/13 61273 Wehrheim Germany REPs Facility ID: F002012	Manufacturing of Dental appliance fabrication material, resin; Temporary dental crown/bridge; Dentine bonding agent/set; Dental casting non-noble alloy; Dental composite resin, Dental etching solution; Dental prosthesis veneer resin, Dental prosthesis priming agent; Dental coating, tooth-desensitizing, professional; Dental composite resin kit



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Certificate

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Manufacturer: **Kulzer GmbH**
Leipziger Str. 2
63450 Hanau
Germany

The scope of certification also covers the following sites:

/03 Kulzer GmbH
Schlätterstr. 2
88142 Wasserburg
Germany

Manufacture and distribution Resin artificial teeth.

REPs Facility ID: F002011

/04 Kulzer SRL
Dietrich Honold, Cladirea C3 1
307370 Sacalaz
Romania

Manufacture of Dental appliance fabrication material, resin; Bite registration rim; Temporary dental crown/bridge; Dental impression material adhesive; Silicone dental impression material; Resin artificial teeth

REPs Facility ID: F007732



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