

Certificate

Certificate No.: MD 1097658-40

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. 16/2013, RDC ANVISA n. 23/2012, 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

TÜV Rheinland[®]

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.: 1097658-100

Issue Date: 2021-12-15

Effective Date: 2021-12-19

Expiry Date: 2024-12-18



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

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9108634777?locale=en
or calling 1-888-743-4652.

Certificate

Certificate No.: MD 1097658-40

Manufacturer: **Kulzer GmbH**

Leipziger Str. 2
63450 Hanau
Germany

Scope: Design and Development, Manufacture and Distribution of Dental anesthesia syringe; Dental appliance fabrication material, ceramic; Dental appliance fabrication material, resin; Dental casting noble alloy; Dental impression tray material; Bite registration rim; Dental crown bridge/temporary; Dentine bonding agent/set; Dental casting non-noble alloy; Dental composite resin; Dental etching solution; Dental impression adhesive; Dental prosthesis veneer resin; Silicone dental impression material and resin artificial teeth.



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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Kulzer GmbH Philip Reis Str. 8/13 61273 Wehrheim Germany REPs ID: F002012	Design and Development, manufacturing of dental materials: Bite registration rim, Dental crown bridge/temporary, Dental appliance fabrication material, resin; Dentine bonding agent/set; Dental casting non-noble alloy; Dental composite resin; Dental etching solution; Dental impression adhesive; Dental prosthesis veneer resin; Silicone dental impression material
/02	Kulzer GmbH Schlätterstr. 2 88142 Wasserburg Germany REPs ID: F002011	Design and development, manufacture and distribution of resin artificial teeth

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