

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1198082-1

Certificate Holder: 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; Dental material cartridge-plunging applicator, two-component, manual; Dental material cartridge-plunging applicator, single-component; Gingival retraction solution; Rubber dam clamp; Rubber dam frame; Rubber dam clamp forceps; Rubber dam kit

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1172551-100

Effective date: 2025-02-04

Expiry date: 2028-02-03

Issue date: 2024-12-17

Replaces certificate SX 1198082-1 issued on 2022-02-04

This certificate can be validated on <https://www.certipedia.com>



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Kulzer GmbH Leipziger Str. 2 63450 Hanau Germany	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; Dental material cartridge-plunging applicator, two-component, manual; Dental material cartridge-plunging applicator, single-component; Gingival retraction solution; Rubber dam clamp; Rubber dam frame; Rubber dam clamp forceps; Rubber dam kit
/02	c/o Kulzer GmbH Philip Reis Str. 8/13 61273 Wehrheim Germany	Manufacture 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; Gingival retraction solution
/03	c/o Kulzer GmbH Schlätterstr. 2 88142 Wasserburg Germany	Manufacture and Distribution of Resin artificial teeth
/04	c/o Kulzer SRL Dietrich Honold nr 1 Cladirea C3 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

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