EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 1198082-1

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

EUDAMED Single Registration No.: DE-MF-000007705

Products: Products of class IIa:

Q010101 - DENTAL RESTORATION DEVICES
Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES - OTHER
Q010201 - DENTAL IMPRESSION MATERIALS
Q010601 - DENTAL ALLOYS
Q010104 - DENTAL PROCEDURE DEVICES - VARIOUS
Q019008 - DENTINAL DESENSITISERS

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial Issuing	2021-12-20
2	Extension and adjustment of scope	2022-08-11
3	Scope extension	2022-11-14

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1119127-10

Effective date: 2022-11-14

Expiry date: 2026-01-14

Issue date: 2022-11-14

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.