

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

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

Authorized representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.: 1195420-10  
Effective date: 2026-01-15  
Expiry date: 2031-01-14  
Issue date: 2025-12-17



Dipl.-Ing. Ute Frenkert  
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This certificate can be validated on <https://www.certipedia.com>

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

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Certificate history		
Revision:	Description:	Issue date:
4	Re-certification. Replaces certificate HZ 1198082-1 Rev. 3 issued 2022-11-14	2025-12-17

