EU Certificate

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

Registration No.:	HZ 1710455-1
Manufacturer:	Cavex Holland BV Fustweg 5 2031 CJ Haarlem Netherlands
EUDAMED Single Registration No.:	NL-MF-000000423
Products:	
	Products of class IIa:
	Q010101 - Dental Restorative Devices
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.:	1212476-10
Effective date:	2026-10-16
Expiry date:	2031-10-15
Issue date:	2026-10-06

Dr. T. Kießling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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:
1	Re-certification Replaces certificate HZ 1710455-1 Rev. 0 issued 2022-08-04	2026-10-06

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