

# EU Certificate

## Quality Management System

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

Registration No.: HZ 1123799-1

Manufacturer: **BEGO Bremer Goldschlägerei  
Wilh. Herbst GmbH & Co. KG**  
Wilhelm-Herbst-Str. 1  
28359 Bremen  
Germany

EUDAMED Single  
Registration No.: DE-MF-000005414

Products: Products of class IIa:

Q010205 - PRE-FORMED RESINS AND DENTAL CROWNS  
Q010601 - DENTAL ALLOYS

Authorised  
representative(s): N/A

#### Certificate history

Revision:	Description:	Issue date:
1	First issuance	2022-10-18
2	Scope extension: addition of Q010601	2023-08-23

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.: 1141199-20

Effective date: 2023-08-23

Expiry date: 2026-09-10

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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.