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 1108110-1
Manufacturer:	**BEGO Implant Systems GmbH & Co. KG** Wilhelm-Herbst-Str. 1 28359 Bremen Germany
EUDAMED Single Registration No.:	DE-MF-000005410
Products:	Products of class IIa: Q010399 SURGICAL DENTAL DEVICES – OTHERS Q010280 - DEVICES FOR PROSTHETIC DENTISTRY - ACCESSORIES Products of class IIb: P010201 DENTAL IMPLANTS AND ACCESSORIES
Authorised representative(s):	**N/A**

Certificate history		
Revision:	Description:	Issue date:
0	Initial issue	2022-04-13
1	Products of class IIa, added to the scope: "Q010280" - DEVICES FOR PROSTHETIC DENTISTRY - ACCESSORIES"	2022-11-11

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.:	1100636-20
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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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.