

Certificate

Certificate No.: MD 1123799-1-1

Manufacturer: BEGO Bremer Goldschlägerei

Wilh, Herbst GmbH & Co. KG

Wilhelm-Herbst-Str. 1

28359 Bremen

Germany

REPs Facility ID: F001085

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance

Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,

RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282,

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,

PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 -

Subparts A to D

Scope: Design and development, manufacture and distribution of alloys,

wires, solders, SLM powders, milling blanks and resins for the

dental field

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1152458-230

Issue Date: 2024-08-29

Effective Date: 2024-08-31

Expiry Date: 2027-08-30



Certification officer: Dipl.-Ing. F. Pilatus TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

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TUV Rheinland of North America, Inc., 400 Beaver Brook Road, Boxborough, MA 01719, USA Tel: (925) 249-9123, Fax: (925) 249-9124