

Certificate

Certificate No.: MD 1085826-50

Manufacturer: BEGO Implant Systems

GmbH & Co. KG

Wilhelm-Herbst-Str. 1

28359 Bremen

Germany

REPs Facility ID: F001096

Certification criteria: ISO 13485:2016

Canada Medical Devices Regulations - Part 1 - SOR 98/282

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

- Subparts A to D

Scope: Design and Development, Production and Distribution of Dental

Implant Systems, Prosthetic Components, Instruments and

Procedure Packs for the Dental Implantology

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.: 1085826-230

Issue Date: 2021-08-16
Effective Date: 2021-08-31

Expiry Date: 2024-08-30



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000010710?locale=en or calling 1-888-743-4652.

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TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460, USA Tel: (925) 249-9123, Fax: (925) 249-9124



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The scope of certification includes the following additional sites:

No. Location Scope

/01 BEGO Implant Systems

GmbH & Co. KG Wilhelm-Herbst-Str. 1 28359 Bremen Germany

REPs Facility ID: F001096

/02 BEGO Implant Systems

GmbH & Co. KG Wilhelm-Herbst-Str. 5 28359 Bremen Germany

REPs Facility ID: F001096

Activities associated with design and development, production and distribution

Activities associated with design and

development

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