Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 19-1619-M

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:
Canada: Medical Devices Regulations – Part 1- SOR/98-282. USA: United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820; 21 CFR Part 821.

Ritter Implants GmbH & Co. KG
Freiburger Str. 45
88400 Biberach, Germany

DUNS number: 34-260-2800
Additional sites covered by QM System: N/A
List of Products: See Annex 2

Design and Development, Manufacture, and Distribution of Dental Implant Systems, Abutments, Surgical Kits, Drills and Instruments.

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

MDSAP Recognized Auditing Organization

Audit Report Reference No.: 18-8082 CA
Current Cycle Start Date: 04-FEB-2019
Certificate Revised Date: N/A

Effective Date:
04-FEB-2019 / ed. 1

Valid Until:
03-FEB-2022

Bradley Chen
Director, Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 19-1619-M / ed. 1
Company Name: ***Ritter Implants GmbH & Co. KG***
Central Office Address: ***Freiburger Str. 45, 88400 Biberach, Germany***

Products	UMDNS	GMDN
Implants	16-744	58949
Abutments	16-393, 17-692	55849
Surgical Kits	16-732	46310
Drills	16-669	46310
Instruments	11-160	46310

---End of list---

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