

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.

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

Facility ID: **F003177**

Additional sites covered by QM System: [See Annex 1](#)

List of Products: [See Annex 2](#)

Scope:

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

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **20-3901 RC**

Certificate Initial Issue Date: **2019-02-04**

Current Cycle Start Date: **2022-02-04**

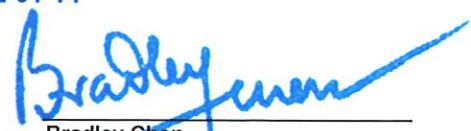
Certificate Revised Date: **2022-01-14**

Effective Date:

2022-02-04 / ed. 2

Valid Until:

2023-02-03



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 19-1619-M / ed. 2
Company Name: Ritter Implants GmbH & Co. KG
Central Office Address: Freiburger Str. 45, 88400 Biberach, Germany



Location

Facility ID: F003177 (Campus)

Headquarters

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

Site 1

Ritter Implants GmbH & Co. KG
Freiburger Str. 32
88400 Biberach, Germany

Scope of Certification

Design and development, management,
purchasing

Warehousing

---End of list---

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Current Cycle Start Date: 2022-02-04
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Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Annex 2, page 1 of 1
(Annex 2 MUST be displayed with the main certificate)

Certificate Registration No. : 19-1619-M / ed. 2
Company Name: Ritter Implants GmbH & Co. KG
Central Office Address: Freiburger Str. 45, 88400 Biberach, Germany



Products	UMDNS	GMDN
Implants	16-744	55849
Abutments	16-396, 17-692	55849
Surgical Kits	16-732	46310
Drills	16-669	46310
Instruments	11-160	46310

---End of list---

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Audit Report Reference No.: 20-3901 RC
Certificate Initial Issue Date: 2019-02-04
Current Cycle Start Date: 2022-02-04
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