

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **20-1618-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:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. **Canada:** Medical Devices Regulations – Part 1- SOR/98-282. **Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Ritter Concept GmbH
Freiburger Straße 45
88400 Biberach, Germany

DUNS number: **33-015-3086**

Additional sites covered by QM System: **N/A**

List of Products: **See Annex 1**

Design and Development, Manufacture, and Service of Dental Treatment Units and Autoclaves for the Area of Dentistry

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.: **19-3789 SA1**

Current Cycle Start Date: **2021-02-03**

Certificate Revised Date: **N/A**

Effective Date:

2021-02-03 / ed. 1

Valid Until:

2023-02-02



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

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



Certificate Registration No. : 20-1618-M / ed. 1
Company Name: Ritter Concept GmbH
Central Office Address: Freiburger Straße 45, 88400 Biberach, Germany

Products	UMDNS	GMDN
Dental Treatment Units	11-165	47144
Autoclaves	16-142	61871

---End of list---

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.: 19-3789 SA1
Current Cycle Start Date: 2021-02-03
Certificate Revised Date: N/A

Effective Date:
2021-02-03 / ed. 1

Valid Until:
2023-02-02

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