

# Certificate

## acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **18-1633-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. **Brazil:** RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009. **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; 21 CFR Part 821.

**Hager & Meisinger GmbH**  
**Hansemannstr. 10**  
**41468 Neuss, Germany**

DUNS number: **31-803-4329**

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

List of Products: **See Annex 2**

**Design, manufacture and sales of tools and instruments for dental and medical application, restorative systems for teeth, dental post systems, bone screws and pins and dental implant systems**

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](mailto:medical-usa@tuv-nord.com)



Audit Report Reference No.: **18-8068 CA**

Certificate Initial Issue Date: **24-DEC-2018**

Certificate Revised Date: **N/A**

Effective Date:

**24-DEC-2018 / ed. 1**

Valid Until:

**23-DEC-2021**



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



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

Certificate Registration No. : 18-1633-M / ed. 1  
Company Name: *Hager & Meisinger GmbH*  
Central Office Address: *Hansemannstr. 10, 41468 Neuss, Germany*

Products	UMDNS	GMDN
Rotary instruments for dental, surgical and medical application	16-668, 16-669, 16-670, 16-412, 10-521, 10-522, 11-341, 15-883	16668, 16669, 16670, 16184, 46940, 31833, 46392, 46938
Dental root post systems	16-700	38609
Dental surgical procedure kits, hand instruments and accessories	15-883, 16-666, 16-667	45147, 13380, 31878, 35702
Sterile rotary instruments and tools	10-521, 16-667, 16-668	61790, 45525
Dental implant systems, restorative systems, abutments and accessories	16-744, 17-841	55847, 55849
Bone screws for fixation of bone blocks	16-744	61837
Bone pins for fixation of membranes	16-744	46645

---End of list---

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