

# 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.

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

Facility ID: **F001161**

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

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

**Scope:**

**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)**

*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



Audit Report Reference No.: **21-3927 RC SPA**

Certificate Initial Issue Date: **2018-12-24**

Current Cycle Start Date: **2021-12-24**

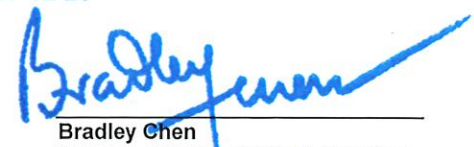
Certificate Revised Date: **2021-12-20**

Effective Date:

**2021-12-24 / ed. 2**

Valid Until:

**2024-12-23**



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

Certificate Registration No. : 18-1633-M / ed. 2  
Company Name: Hager & Meisinger GmbH  
Central Office Address: Hansemannstr. 10, 41468 Neuss, Germany



**Location**

**Scope of Certification**

**Facility ID: F00001161 (Campus)**

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

Design and development, management,  
production, purchasing

**Site 1**  
Hager & Meisinger GmbH  
Hansemannstr. 75  
41468 Neuss, Germany

Warehousing

---End of list---

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Products	UMDNS	GMDN
Bone Screws	16-744	61837
Bone Pin (Membrane fixation)	16-744	46645
Dental Implant System OKTAGON	16-744, 17-841	55849, 44879, 44880, 61647
Bur, dental, steel	16-669	16669
Bur, dental, diamond	16-670	16670, 45525
Bur, dental, carbide	16-668	16668, 61790
Surgical burs	15-833, 10-522, 15-204	10552, 43311, 14147, 46391, 46392, 45329, 35289, 17507, 45527, 64025
Flexible polishers	10-521, 16-412	46940, 31833
Ceramic abrasive	10-521	31833, 63517
Kits, Procedure packs (Bone management)	16-744	45147, 46940, 55847
Dental root (filling) post systems	16-700	44880, 38609

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Products	UMDNS	GMDN
Manual instruments and tools	16-666, 16-667	12726, 13380, 15047, 15713, 17507, 18129, 31335, 31776, 31822, 31846, 31878, 32312, 33968, 35095, 38759, 41660, 43962, 44806, 44887, 44901, 45147, 45320, 45329, 45713, 47830, 47831, 57789, 62466, 62470, 64304, 64314
Polishing paste	16-699	11168
Dental Implant System myplant	16-744, 17-841	55849, 44879, 44880, 61647
Rotary instruments for spine surgery	15-621	45553
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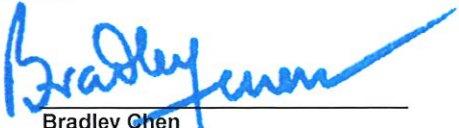
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