

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. 665/2022, RDC ANVISA n. 551/2021, 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

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: 21-3927 RC-SA3

Initial Certification Date: 2018-12-24

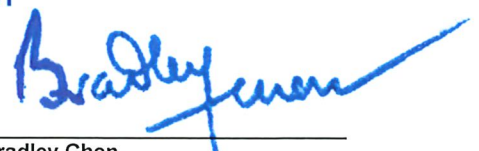
Current Cycle Start Date: 2023-03-01

Effective Date:

2023-03-01 / ed. 3

Valid Until:

2026-02-28



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. : 18-1633-M / ed. 3
Company Name: Hager & Meisinger GmbH
Central (HQ) Office Address: Hansemannstr. 10, 41468 Neuss, Germany



Location

Scope of Certification

Facility ID: F001161 (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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Annex 2, page 1 of 2

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Company Name: Hager & Meisinger GmbH
Central (HQ) Office Address: Hansemannstr. 10, 41468 Neuss, Germany



| 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 |

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Central (HQ) Office Address: Hansemannstr. 10, 41468 Neuss, Germany



| Products | UMDNS | GMDN |
|-----------------------------------------|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Kits, Procedure packs (Bone management) | 16-744 | 45147, 46940, 55847 |
| Dental root (filling) post systems | 16-700 | 44880, 38609 |
| 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 |

---End of list---

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