

# Certificate

Management system as per  
**ISO 13485:2016 (MDSAP)**

The Auditing Organization TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

**Hager & Meisinger GmbH**  
**Hansemann Str. 10**  
**41468 Neuss**  
**Germany**  
**[Facility ID: F001161]**

**With „Additional Sites“ according to the annex 1**

Operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for 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, PMD Act (as applicable).

**United States:** 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

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

Certificate Registration No. 26-1603-M  
Project No. 25-4129 RC-SA2-CSA

Effective Date: 2026-03-01  
Expiry Date: 2029-02-28  
Initial Certification Date: 2018-12-24

Salem, NH; 2026-02-04, Edition 1

TUV USA, Inc.  
215 Main Street,  
Salem, New Hampshire 03079  
United States of America  
[www.tuv-nord.com/us](http://www.tuv-nord.com/us)  
TÜV®

  
Auditing Organization TUV USA, Inc.

The validity of this certificate may be obtained by contacting TUV USA at: +1 (603) 870-8023 (option 1) or via Email: [medical-usa@tuv-nord.com](mailto:medical-usa@tuv-nord.com)

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TUV USA, Inc. is recognized under the Medical Device Single Audit Program

# Annex 1

to Certificate Registration No. 26-1603-M  
**ISO 13485:2016 (MDSAP)**

**Hager & Meisinger GmbH**  
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**41468 Neuss**  
**Germany**  
**[Facility ID: F001161]**

Validity of Annex depends on the validity of the main certificate.

<b>Certificate Registration No.</b>	<b>Location</b>	<b>Scope</b>
26-1603-M [Facility ID: F001161]	Hager & Meisinger GmbH Hansemann Str. 10 41468 Neuss Germany	Headquarters – Design and development, management, production, purchasing
26-1603-M-001 [Facility ID: F001161]	Hager & Meisinger GmbH Hansemann Str. 75 41468 Neuss Germany	Warehousing

**End of the List**

Salem, NH; 2026-02-04, Edition 1

TUV USA, Inc.  
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Salem, New Hampshire 03079  
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[www.tuv-nord.com/us](http://www.tuv-nord.com/us)  
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