

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

SCHEU-Dental GmbH
Am Burgberg 20
58642 Iserlohn
Germany
[Facility ID: F004436]

With „Additional Sites“ according to the annex 1

With „Products“ according to the annex 2

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 distribution of orthodontic medical devices and dental laboratory equipment

Certificate Registration No. 26-1605-M

Project No. 25-4134 RC-SA1

Effective Date: 2026-03-03

Expiry Date: 2029-03-02

Initial Certification Date: 2021-03-03

Salem, NH; 2026-03-03, Edition 1

TUV USA, Inc.
215 Main Street,
Salem, New Hampshire 03079
United States of America
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

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

Annex 1

to Certificate Registration No. 26-1605-M
ISO 13485:2016 (MDSAP)

SCHEU-DENTAL GmbH
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58642 Iserlohn
Germany
[Facility ID: F004436]

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

Certificate Registration No.	Location	Scope
26-1605-M [Facility ID: F004436]	SCHEU-DENTAL GmbH Am Burgberg 20 58642 Iserlohn Germany	Headquarters Design, manufacture and distribution
26-1605-M-001 [Facility ID: F004436]	SCHEU-DENTAL GmbH Am Burgberg 13 58642 Iserlohn Germany	Manufacture

End of the List

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Annex 2

to Certificate Registration No. 26-1605-M
ISO 13485:2016 (MDSAP)

SCHEU-DENTAL GmbH
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Products	UMDNS	GMDN
EXPANSION SCREWS	17-802	17802
HERBST / IST APPLIANCES	17-802	17802
DENTAL SLEEP MEDICINE	17-802	17802
BONDING AGENT	17-114	34782
PRESSURE MOULDING MATERIAL	16-697	58288
LIGHT CURING MATERIAL	16-697	58288
POWER GRIPS	16-360	44732
BITE REGISTRATION	16-350	18083
IMPRESSION TRAY HANDLES	16-350	16350
DENTAL WIRES	16-204	16204

Continued next page

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Annex 2

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ISO 13485:2016 (MDSAP)

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Products	UMDNS	GMDN
ACTIVATOR TUBES	16-204	16204
CLASPS AND BARS	16-204	16204
PLIERS	15-710	33209
LABORATORY EQUIPMENT	N/A	N/A

End of the List

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