

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. 25-1607-M
Project No. 22-4005 SA2-SPA-CSA

Issue Date: 2023-03-08
Reissue Date: 2025-02-08
Expiry Date: 2026-03-02
Initial Certification Date: 2021-03-03

Salem, NH; 2025-02-08, Edition 1


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

TUV USA, Inc.
215 Main Street, Salem, NH 03079
United States of America
www.tuv-nord.com/us
TÜV ®

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

Annex 1

to Certificate Registration No. 25-1607-M
ISO 13485:2016 (MDSAP)

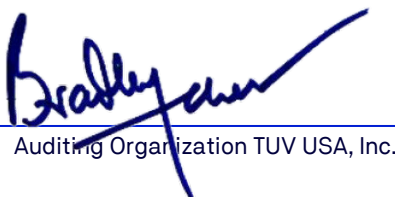
SCHEU-DENTAL GmbH
Am Burgberg 20
58642 Iserlohn
Germany
[Facility ID: F004436]

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

Certificate Registration No.	Location	Scope
25-1607-M [F004436]	SCHEU-DENTAL GmbH Am Burgberg 20 58642 Iserlohn Germany	Headquarters Design, manufacture and distribution
25-1607-M -001 [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. 25-1607-M
ISO 13485:2016 (MDSAP)

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

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

Products	UMDNS	GMDN
Expansion Screws	17-802	17802
Herbst / IST Appliances	17-802	17802
Dental Sleep Medicine	17-802	17802
Dental Wires	16-204	16204
Clasps and Bars	16-204	16204
Activator Tubes	16-204	16204
Pressure Moulding Material	16-697	58288
Light Curing Material	16-697	58288
Power Grips	16-360	44732
Pliers	15-710	33209

Continued next page

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Annex 2

to Certificate Registration No. 25-1607-M
ISO 13485:2016 (MDSAP)

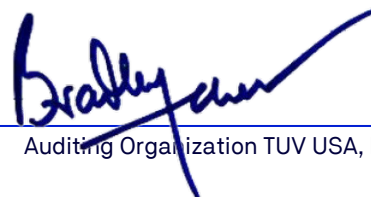
SCHEU-DENTAL GmbH
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Products	UMDNS	GMDN
Bite Registration	16-350	18083
Impression Tray Handles	16-350	16350
Bonding Agent	17-114	34782
Laboratory Machines and Products JMDN: 70906000, 70896000, 70750010	N/A	N/A

End of the List

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