

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 21-1601-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.

SCHEU-DENTAL GmbH
Am Burgberg 20
58642 Iserlohn, Germany

Facility ID: **F004436**

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

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

Scope:

Design, Manufacturing and Distribution of Orthodontic Medical Devices

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.: **22-4005 RC-SA3**

Initial Certification Date: **2021-03-03**

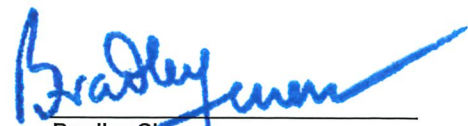
Current Cycle Start Date: **2023-03-08**

Effective Date:

2023-03-08 / ed. 2

Valid Until:

2026-03-02



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

Certificate Registration No. : 21-1601-M / ed. 2
Company Name: SCHEU-DENTAL GmbH
Central (HQ) Office Address: Am Burgberg 20, 58642 Iserlohn, Germany



Location

Scope of Certification

Facility ID: F004436 (Campus)

Headquarters
SCHEU-DENTAL GmbH
Am Burgberg 20
58642 Iserlohn, Germany

Design, manufacturing and distribution

Site 1
SCHEU-DENTAL GmbH
Am Burgberg 13
58642 Iserlohn, Germany

Manufacturing

---End of list---

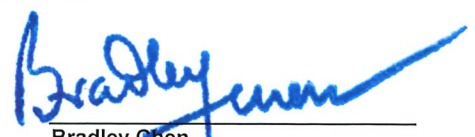
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Products	UMDNS	GMDN
Expansion Screws	17-802	17802
Herbst / IST Appliances	17-802	17802
Dental Sleep Medicine	17-802	17802
Dental Wires	16-204	16204
Clasps and Bars	16-204	16204
Activator Tubes	16-204	16204
Pressure Moulding Material	16-697	58288
Light Curing Material	16-697	58288
Power Grips	16-360	44732
Pliers	15-710	33209
Bite Registration	16-350	18083
Impression Tray Handles	16-350	16350
Bonding Agent	17-114	34782
Laboratory Machines and Products JMDN: 70906000, 70896000	N/A	N/A

---End of list---

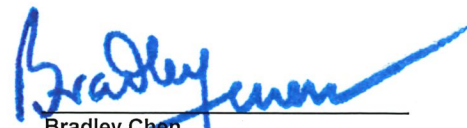
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