Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 19-1634-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.

Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna, Germany

Facility ID: F005235
Additional sites covered by QM System: N/A
List of Products: See Annex 1

Scope:

Design and development, manufacture and distribution of medical devices for hearing aids (3D printing, silicones, resins, light polymerization, cleaning and disinfectant products)

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Audit Report Reference No.: 21-3967 RC-SA3
Initial Certification Date: 2019-12-15
Current Cycle Start Date: 2022-12-15

Effective Date:
2022-12-15 / ed. 2

Valid Until:
2025-12-14

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

Certificate Registration No. : **19-1634-M / ed. 2**
Company Name: ***Dreve Otoplastik GmbH***
Central (HQ) Office Address: ***Max-Planck-Straße 31, 59423 Unna, Germany***

Products	UMDNS	GMDN
Earmould impression kit	16-646	43783
Hearing aid and earmould material (Earmould, custom-made)	11-967	41228
Air-conduction hearing aid acoustic tube	14-238	62260
Medical device disinfectant	N/A	47631
Medical device cleaning / disinfection wipe	N/A	58077
Hearing aid maintenance kit	N/A	64219
Moisture / lubrication otic solution	N/A	58807

---End of list---

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