C E R T I F I C A T E

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

Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna, Germany
[Facility ID: F005235]

with the locations according to annex 1
with products according to 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, **United States:** 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

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

Certificate Registration No. 19-1634-M
Audit Report No. 21-3967 SA1-SA4

Valid from 2024-02-21
Valid until 2025-12-14
Initial certification 2019-12-15

Recognized Auditing Organization
at TUV USA, Inc.

Salem, NH 2024-04-13, ed. 3

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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

The validity of this certification document can be obtained by contacting the TUV USA, Inc, office.
Tel: 001-603-870-8023 (option 1), Email: medical-usa@tuv-nord.com

ANNEX 1

to Certificate Registration No. 19-1634-M
ISO 13485:2016 (MDSAP)

Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna, Germany
[Facility ID: F005235]

Location	Scope
Dreve Otoplastik GmbH Max-Planck-Straße 31 59423 Unna, Germany [Facility ID: F005235]	Manufacture and distribution of medical devices for hearing aids (3D printing, thermoforming technique, silicones, resins, light polymerization, cleaning products and disinfectant products)
Dreve Otoplastik GmbH Einsteinstraße 38 59423 Unna, Germany [Facility ID: F005235]	Design and development of medical devices for hearing aids (3D printing, silicones, resins, light polymerization, cleaning and disinfectant products)

End of the List

Recognized Auditing Organization
at TUV USA, Inc.

Salem, NH 2024-04-13, ed. 3

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ANNEX 2

to Certificate Registration No. 19-1634-M
ISO 13485:2016 (MDSAP)

Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna, Germany
[Facility ID: F005235]

Products	UMDNS	GMDN
Earmould impression kit	16-646	43783
Hearing aid and earmould material (earmould, customer-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 the list

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