

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

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



Recognized Auditing Organization
at TUV USA, Inc.

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

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

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

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

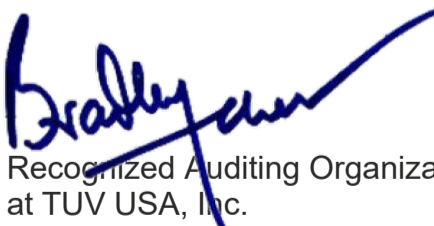
Dreve Otoplastik GmbH
Einsteinstraße 38
59423 Unna, Germany
[Facility ID: F005235]

Scope

Manufacture and distribution of medical devices for hearing aids (3D printing, thermoforming technique, silicones, resins, light polymerization, cleaning products and disinfectant products)

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

TUV USA, Inc.

215 Main Street, Salem, NH 03079, USA

www.tuv-nord.com/us



*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

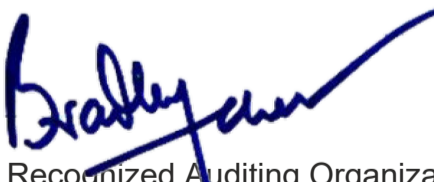
ANNEX 2

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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