

CERTIFICATE

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TÜV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

DeVilbiss Healthcare LLC
100 DeVilbiss Drive
Somerset, Pennsylvania 15501
United States of America
[Facility ID: F001156]

with the locations according to Annex: N/A
with products according to Annex 1

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).

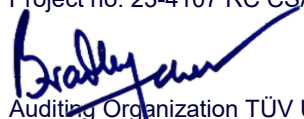
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Design, Manufacture, Service and Distribution of Respiratory Care Products

Certificate Registration No. 24-1610-M
Project no. 23-4107 RC CSA

Valid from 2024-07-05
Valid until 2027-07-04
Initial Certification: 2018-07-05


Auditing Organization TÜV USA, Inc.

Salem, NH 2024-06-03, Edition 1



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

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

TÜV USA Inc.

215 Main Street

Salem, NH 03079

United States of America

tuv-nord.com/us

Annex 1

to Certificate Registration No. 24-1610-M

ISO 13485:2016 (MDSAP)

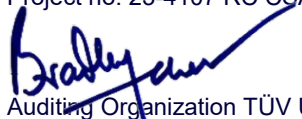
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Validity of Annex depends on the validity of the main certificate.

Products	UMDNS	GMDN
Suction Kits and Accessories - Suction Units	13-846	48000
Compressors and Accessories - Compressor	15-045	35457
Oxygen Concentrators and Accessories - iFILL Oxygen Cylinder with Continuous Flow Regulator	18-076	43438
- iGo Portable Oxygen System	12-873	31321
- 5 and 10 Liter Compact Oxygen Concentrator	12-873	12873

Continued on page 2

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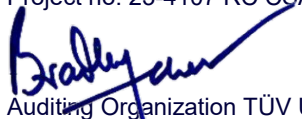
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Oxygen Delivery Units, Controlled and Accessories - Compact PulseDose Conserving Device - PulseDose Oxygen Conserving Cylinder/ifiLL Oxygen Cylinder with Continuous Flow Regulator	18-076	43438
Professional ENT Instruments - Atomizers - Powder Blowers - Nebulizers - Irrigation Syringe	10-226 12-144 12-172 13-942	16529 33466 N/A 35390

End of List

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