

# Certificate

acc. to **ISO 13485:2016**

**Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes**

**Certificate Registration No.: 18-1605-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.

**DeVilbiss Healthcare LLC**  
**100 DeVilbiss Drive**  
**Somerset, Pennsylvania 15501, USA**

**Facility ID: F001156**

Additional sites covered by QM System: *N/A*

List of Products: *See Annex 1*

**Scope:**

**Design, Manufacture, Service and Distribution of Respiratory Care 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](mailto:medical-usa@tuv-nord.com)**

*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



**Audit Report Reference No.: 20-3889 SA2 SA4 SA1 SPA**

**Initial Certification Date: 2018-07-05**

**Current Cycle Start Date: 2021-07-05**

**Effective Date:**

**2023-08-15 / ed. 4**

**Valid Until:**

**2024-07-04**

A handwritten signature in blue ink, which appears to read 'Bradley Chen', is written over a horizontal line.

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

(Annex 1 MUST be displayed with the main certificate)

Certificate Registration No. : 18-1605-M / ed. 4  
Company Name: DeVilbiss Healthcare LLC  
Central (HQ) Office Address: 100 DeVilbiss Drive  
Somerset, Pennsylvania 15501, USA

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

--- End of list---

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](mailto:medical-usa@tuv-nord.com)

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: 20-3889 SA2 SA4 SA1 SPA

Initial Certification Date: 2018-07-05

Current Cycle Start Date: 2021-07-05

Effective Date:  
2023-08-15 / ed. 4

Valid Until:  
2024-07-04

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