

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. 16/2013; RDC ANVISA n. 23/2012; 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, PA 15501, USA

Facility ID: **F001156**

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

List of Products: **See Annex 1**

Scope:

**Design, Manufacturing, 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

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **20-3889 RC SA2**

Certificate Initial Issue Date: **2018-07-05**

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

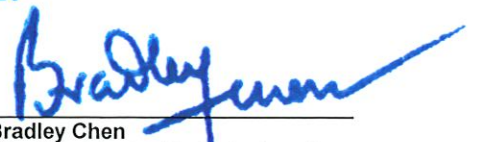
Certificate Revised Date: **2021-05-26**

Effective Date:

2021-07-05 / ed. 2

Valid Until:

2022-07-04



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

Certificate Registration No. : 18-1605-M / ed. 2
Company Name: DeVilbiss Healthcare LLC
Central Office Address: 100 DeVilbiss Drive, Somerset, PA 15501, USA



Products	UMDNS	GMDN
CPAP Systems	11001	60711
Suction Units	13846	48000
Compressor	15045	35457
Compact PulseDose Conserving Device	18076	43438
PulseDose Oxygen Conserving Cylinder	18076	43438
iFill Personal Oxygen Station	18076	43438
iGo Portable Oxygen System	12873	31321
5 and 10 Liter Compact Oxygen Concentrator	12873	12873

---End of list---

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