

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, PA 15501, USA

Facility ID: **F001156**

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

List of Products: **N/A**

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)

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TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **20-3889 SA1 SA3 RC**

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

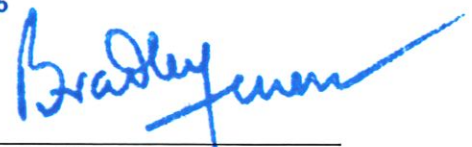
Current Cycle Start Date: **2021-07-05**

Effective Date:

2022-07-05 / ed. 3

Valid Until:

2023-07-04



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