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)
215 Main Street, Suite 1, Salem, NH 03079, USA
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TUV USA, Inc. is an MDSAP Recognised Auditing Organization

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Audit Report Reference No.: 20-3889 SA1 SA3 RC
Initial Certification Date: 2018-07-05
Current Cycle Start Date: 2021-07-05

Effective Date:
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Valid Until:
2023-07-04

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