Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Inovo, Inc.
401 Leonard Blvd N
Lehigh Acres
Florida
33971
USA

DUNS Number: 01-595-4530

Holds certificate No: **MDSAP 683490**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia – Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure [if design controls are excluded from the certification]; Brasil – 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 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design and Development, Production, Distribution, and Servicing of Respiratory Devices.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-06-22 Effective Date: 2018-06-22 Expiry date: 2021-06-21

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 18-1605

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 820; 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D

DeVilbiss Healthcare LLC
100 DeVilbiss Drive
Somerset, PA 15501, USA

DUNS number: 96-21-75894
Additional sites covered by QM System: Annex 1 - N/A
List of Products: See Annex 2

Design, Manufacturing, Service, and Distribution of Respiratory Care Products and Accessories

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office

TUV USA, Inc. (Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079
Tel: 001-603-870-8023, Fax: 001-603-870-8026

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
MDSAP Authorized Auditing Organization

Audit Report Reference No: 18-8001 SA1-CA
Initial Issue Date: 05-JUL-2018

Effective Date:
05-JUL-2018 / ed. 1

Expiry Date:
04-JUL-2021

Bradley Chen
Director, Medical Products Division
TUV USA, Inc.

Annex 2, page 1 of 1
(Annex 2 MUST be displayed with the main certificate)

Certificate Registration No. : 18-1605 / ed. 1
Company Name: ***DeVilbiss Healthcare LLC***
Central Office Address: ***100 DeVilbiss Drive, Somerset, PA 15501, USA***

Products	UMDNS	GMDN
Compressors	10-971	---
CPAP Systems	11-001	---
Nebulizers	12-712	---
Suction Kit Devices	13-846	---
Oxygen Concentrators	12-873	---
Oxygen Delivery Units, Controlled	18-076	---

---End of list---

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office

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Bradley Chen
Director, Medical Products Division
TUV USA, Inc.