CERTIFICATE

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TÜV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

Inovo, Inc.
401 Leonard Boulevard North,
Lehigh Acres, Florida 33971
United States of America
[Facility ID: F005374]

with the locations according to Annex: N/A
with products according to Annex: 1

operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for 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, PMD Act (as applicable).
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Design and Development, Production, and Distribution of Respiratory and Pediatric Rehabilitation Products
Contract Manufacturing and Service of Respiratory Products

Certificate Registration No. 24-1612-M
Project no. 23-4108 RC

Valid from 2024-06-22
Valid until 2027-06-21
Initial Certification: 2021-03-26

Auditing Organization TÜV USA, Inc.

Salem, NH 2024-06-06, Edition 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TUV USA, Inc. is recognized under the Medical Device Single Audit Program

The validity of this certification document can be obtained by contacting the TUV USA, Inc, office. Tel: 001-603-870-8023 (option 1), Email: medical-usa@tuv-nord.com

Annex 1

to Certificate Registration No. 24-1612-M

ISO 13485:2016 (MDSAP)

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Validity of Annex depends on the validity of the main certificate.

Products	UMDNS	GMDN
Bonsai Series Pneumatic Oxygen Conserver	18076	43438
Evolution Series Electronic Oxygen Conserver	18076	43438
Oxymizer Disposable Oxygen Conserving Device	12700	44472
SmartDose Mini Auto-Adjusting Oxygen Conserver	18076	43438
Regulators	13320	64303

Continue on page 2

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Products	UMDNS	GMDN
Toileting	10788	--
Bath Lift	12330	--
Bath Wrap-Around	10788	--
Bath Transfer	15693	--
Bath Transfer Chair	10788	--
Seating and Positioning	10797	--
Wheeled Mobility	14449	--

End of List

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