

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 21-1604-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.

Inovo, Inc.
401 Leonard Blvd. North
Lehigh Acres, Florida 33974, USA

Facility ID: **F005374**

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

List of Products: **See Annex 1**

Scope:

**Design and Development, Production, Distribution, and Service of
Respiratory Products.**

Contract Manufacturing of Pediatric Rehabilitation 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.: 21-3935 SA2-SPA

Initial Certification Date: 2021-03-26

Current Cycle Start Date: 2021-06-22

Effective Date:

2023-07-06 / ed. 4

Valid Until:

2024-06-21

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

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Company Name: Inovo, Inc.
Central (HQ) Office Address: 401 Leonard Blvd. North
Lehigh Acres, Florida 33974, USA

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
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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