

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

**Inovo, Inc.**  
**401 Leonard Blvd. North**  
**Lehigh Acres, FL 33971, USA**

Facility ID: **F005374**

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

List of Products: **N/A**

Scope:

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

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*



Audit Report Reference No.: **21-3935 TRF**

Certificate Initial Issue Date: **2021-03-26**

Current Cycle Start Date: **2018-06-22**

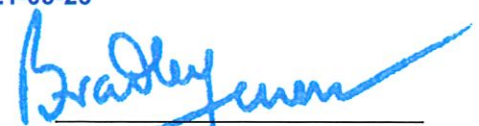
Certificate Revised Date: **2021-03-26**

Effective Date:

**2021-03-26 / ed. 1**

Valid Until:

**2021-06-21**



**Bradley Chen**  
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TUV USA, Inc.