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
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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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