

Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 21-1603-Q

The Certification Body TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization's quality management system is in conformance with ISO 13485:2016 for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

> Inovo, Inc. 401 Leonard Boulevard North, Lehigh Acres, Florida 33971 **United States of America**

Additional sites covered by QM System: N/A

Scope:

Design and Development, Production, and Distribution of Respiratory and **Pediatric Rehabilitation Products Contract Manufacturing and Service of Respiratory 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, Salem, New Hampshire 03079, USA

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Audit Report Reference No.: 23-4108 RC Initial Certification Date: 2021-03-26 Current Cycle Start Date: 2024-06-22

Effective Date:

Valid Until: 2027-06-21

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Vice President - Medical, Americas **Medical Products Division** TUV USA, Inc.

ANSI National Accreditation Board

ACCREDITED

MANAGEMENT SYSTEMS

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