



America

CERTIFICATE

No. QS6 094965 0004 Rev. 02

Certificate Holder: **Morgan Scientific, Inc.**
151 Essex Street
Haverhill MA 01832
USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture, Installation, and Distribution of Pulmonary Function (PFT) Software and Hospital Information Interface for use with PFT Equipment; Distribution of PFT Equipment, Gas Mixing Bags, Air Filtrations Chemicals, and Single-Use Filters; Service and Installation of PFT Equipment**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001705**

Effective Date: **2022-01-07**

Expiry Date: **2024-11-25**

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Date of Issue: 2022-01-11

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803

- 21 CFR Part 806

- 21 CFR Part 807 – Subparts A to D

- 21 CFR Part 820

Facility(ies):

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