



America

CERTIFICATE

No. QS6 024751 0026 Rev. 04

Certificate Holder: **Quest Medical, Inc.**
One Allentown Parkway
Allen TX 75002-4211
USA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture, Distribution, Servicing of Cardiopulmonary Bypass Vascular Cannulas, Tubing and Catheters, Cardiovascular Surgical Devices, Fluid Delivery Devices, Cardioplegia Delivery System, and Manual Ophthalmic Surgical Devices for the areas of Cardiovascular, Ophthalmology, Anesthesiology and General Surgery**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 024751 0026 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:QS6_024751_0026_Rev.04)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001322**
Report No.: **72199175**
Effective Date: **2025-02-24**
Expiry Date: **2028-02-23**

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Date of Issue: 2025-01-08

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

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 Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

Quest Medical, Inc.

One Allentown Parkway, Allen TX 75002-4211, USA

Facility Scopes:

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