




America

CERTIFICATE

No. QS6 024751 0026 Rev. 00

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

Certification Mark: 

Scope of Certificate: Design and Development, Manufacture, Distribution, Installation and Servicing of Cardiopulmonary Bypass Vascular Cannulas, Tubing and Catheters, Cardiovascular Surgical Devices, Fluid Delivery Devices, Cardioplegia Delivery System, Activated Coagulation Time Monitors, 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, USA FDA, MHLW / PMDA. 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 <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No: 04-181-0693

Effective Date: 2019-02-24

Expiry Date: 2022-02-23

Page 1 of 2
Date of Issue: 2019-03-05

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

Quest Medical, Inc.
One Allentown Parkway, Allen TX 75002-4211, USA

Facility Scopes:

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Page 2 of 2

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