



Product Service

# CERTIFICATE

No. Q1N 17 05 24751 018

**Holder of Certificate:** **Quest Medical, Inc.**

One Allentown Parkway  
Allen TX 75002-4211  
USA

**Facility(ies):**

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production, 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**

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 72124221

**Valid from:** 2017-08-03

**Valid until:** 2020-07-29

**Date,** 2017-08-03

Stefan Preiß

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