



America

# CERTIFICATE

No. QS6 083562 0018 Rev. 00

**Certificate Holder:** Spacelabs Healthcare, Inc.  
35301 SE Center Street  
Snoqualmie WA 98065  
USA

**Certification Mark:**



**Scope of Certificate:** See Page 2 for Overall Scope Statement.

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

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, 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 <https://www.tuev-sued.de/product-testing/certificates>

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

**DUNS No:** 14-558-1588

**Effective Date:** 2019-02-22

**Expiry Date:** 2022-02-21

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Date of Issue: 2019-03-15

( Arie Henkin )  
Manager, Certification Body MHS



# C E R T I F I C A T E

No. QS6 083562 0018 Rev. 00

**Facility(ies):** Spacelabs Healthcare, Inc.  
35301 SE Center Street, Snoqualmie WA 98065, USA

**Facility Scopes:** Design and Development, Production, Installation, Service, and Distribution of Medical Physiological Monitors, Clinical Information Systems; Manufacturing and Distribution of Bedside Monitors, Physiologic Parameter Modules (ECG, Temperature, Capnography, etc.) (Cables and Sensors), Module Housings, Central Station Monitors, Remote and Slave Monitors, Telemetry Transmitters, Telemetry Receiver Modules, Telemetry Antenna Systems, Physiologic Data Acquisition and Management Systems, External Monitor Interfaces, Multigas Analyzers, Printing Systems, Wireless Network Interfaces, Clinical Information Systems; Contract Manufacturing and Distribution of Monitoring Equipment used in Cardiology and Anesthesia Delivery Systems including Ventilators  
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( Arie Henkin )  
Manager, Certification Body MHS

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