



America

CERTIFICATE

No. QS6 083562 0018 Rev. 02

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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_083562_0018_Rev.02

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

REPs Facility ID: **F001731**
Report No.: **72192618**
Effective Date: **2024-02-02**
Expiry Date: **2027-02-01**

Page 1 of 3

Date of Issue: 2024-03-26

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS6 083562 0018 Rev. 02

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. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

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

Overall Scope Statement:

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

Page 2 of 3

Date of Issue: 2024-03-26

(Renee Walker)
 Director, US Certification Body, MHS



America

CERTIFICATE

No. QS6 083562 0018 Rev. 02

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
REPs Facility ID: F001731

Page 3 of 3
Date of Issue: 2024-03-26

(Renee Walker)
Director, US Certification Body, MHS