



America

CERTIFICATE

No. QS6 070231 0019 Rev. 00

Certificate Holder: Spacelabs Healthcare Ltd.
Unit B, Foxholes Centre
John Tate Road
Hertford, Hertfordshire SG13 7DT
UNITED KINGDOM

Certification Mark:



Scope of Certificate: Design, Manufacture, and Service of ECG Recorders, Ambulatory ECG and NIBP Recorders and Receiving Stations, ECG Analysers, ECG Stress Test Systems, Cardiac Information Management Systems, Anaesthetic and Ventilation Equipment

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: 21-670-7349

Effective Date: 2019-12-19

Expiry Date: 2022-12-18

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(Dawn M. Tibodeau)
Manager, 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

United States

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

Facility(ies):

Spacelabs Healthcare Ltd.
 Unit B, Foxholes Centre, John Tate Road, Hertford, Hertfordshire
 SG13 7DT, UNITED KINGDOM

Spacelabs Healthcare Ltd.
 43 Moray Place, Edinburgh, Lothian EH3 6BT, UNITED KINGDOM

Facility Scopes:

Spacelabs Healthcare Ltd.

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 SG13 7DT, UNITED KINGDOM

Design, Manufacture, and Service of ECG Recorders, Ambulatory
 ECG and NIBP Recorders and Receiving Stations, ECG Analysers,
 ECG Stress Test Systems, Cardiac Information Management
 Systems, Anaesthetic and Ventilation Equipment
 DUNS No: 21-670-7349

Spacelabs Healthcare Ltd.

43 Moray Place, Edinburgh, Lothian EH3 6BT, UNITED KINGDOM

Design of ECG Recorders, Ambulatory ECG and NIBP Recorders
 ECG Analysers, Cardiac Information Management Systems,
 Receiving Stations, ECG Stress Test Systems
 DUNS No: 21-759-4889

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