

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Spacelabs Healthcare, Inc.
35301 SE Center Street
Snoqualmie
Washington
98065
USA

Facility ID Number: F007164

Holds Certificate No:

MDSAP 798937

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

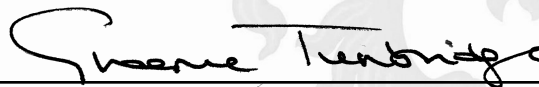
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-03-11

Effective Date: 2024-03-11

Expiry Date: 2027-03-10



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 798937**

Registered Scope:

Design and development, manufacture, installation, servicing and distribution of vital and non-vital physiological monitoring devices, clinical information software, pressure infusion cuffs, and blood pressure cuffs.

Contract manufacture of non-vital physiological monitoring devices and clinical information software, and blood pressure cuffs.



Original Registration Date: 2024-03-11

Effective Date: 2024-03-11

Expiry Date: 2027-03-10

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This certificate remains the property of BSI and shall be returned immediately upon request.

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To be read in conjunction with the scope above or the attached appendix.

Certificate No: **MDSAP 798937**

Location	Registered Activities
Spacelabs Healthcare, Inc. 35301 SE Center Street Snoqualmie Washington 98065 USA Facility ID Number: F007164	Design and development, manufacture, installation, servicing and distribution of vital and non-vital physiological monitoring devices, clinical information software, pressure infusion cuffs, blood pressure cuffs, and accessories for these devices. Contract manufacture of non-vital physiological monitoring devices and clinical information software, and blood pressure cuffs.
Spacelabs Ltd (Hertford) Unit B Foxholes Centre John Tate Road Hertford Hertfordshire SG13 7DT United Kingdom Facility ID Number: F007201	Installation, servicing and distribution of vital and non-vital physiological monitoring devices, clinical information software, pressure infusion cuffs, blood pressure cuffs, and accessories for these devices.
Spacelabs Ltd (Edinburgh) 43 Moray Place Edinburgh Lothian EH3 6BT United Kingdom Facility ID Number: F007202	Design and development of non-vital physiological monitoring devices, clinical information software, and accessories for these devices.

Original Registration Date: 2024-03-11 Effective Date: 2024-03-11 Expiry Date: 2027-03-10

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