



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Spacelabs Healthcare, Inc.

35301 SE Center Street Snoqualmie Washington 98065 USA

Holds Certificate Number: MD 798934

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Development, Manufacture, Installation, Service and Distribution of monitoring devices of vital and non-vital physiological parameters, clinical information software, pressure infusion cuffs, blood pressure cuffs and accessories for these medical devices. Contract Manufacture, of monitoring devices of non-vital physiological parameters and clinical information software, blood pressure cuffs and accessories for these medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-06-20 Effective Date: 2024-06-20 Latest Revision Date: 2024-06-20 Expiry Date: 2027-03-10

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...making excellence a habit."





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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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Location Registered Activities Spacelabs Healthcare, Inc. Design and Development, Manufacture, Installation, Service and Distribution of monitoring devices of vital and non-vital 35301 SE Center Street physiological parameters, clinical information software, Snoqualmie pressure infusion cuffs, blood pressure cuffs and accessories Washington for these medical devices. 98065 Contract Manufacture, of monitoring devices of non-vital USA physiological parameters and clinical information software, blood pressure cuffs and accessories for these medical devices. Spacelabs Ltd (Hertford) Installation, Service and Distribution of monitoring devices of vital and non- vital physiological parameters, clinical Unit B Foxholes Centre information software, pressure infusion cuffs, blood pressure John Tate Road cuffs and accessories for these medical devices. Hertford Hertfordshire SG13 7DT United Kingdom Design and Development of monitoring devices of non-vital Spacelabs Ltd (Edinburgh)

Spacelabs Ltd (Edinburgh)
43 Moray Place
Edinburgh
Lothian
EH3 6BT
United Kingdom

Design and Development of monitoring devices of non-vital physiological parameters and clinical information software and Accessories for these medical devices.

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