

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Huntleigh Healthcare Ltd**
35 Portmanmoor Road
Cardiff
CF24 5HN
United Kingdom

Facility ID Number: F005447

Holds Certificate No: **MDSAP 747619**

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

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

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 Global Regulatory & Quality

Original Registration Date: 2016-05-01

Effective Date: 2024-12-17

Expiry Date: 2027-12-16



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 747619**

Registered Scope:

Design, manufacture, service and distribution of assessment, treatment and monitoring equipment including:

- Vascular assessment devices with sterile vascular probes, nonsterile vascular probes, power adaptor and garments
- Vascular treatment devices and Vital signs monitors with nonsterile garments.
- Fetal monitors with non-sterile obstetric probes, transducers, event markers, FECG Leg plate, reusable & disposable belts, reusable spo2 leads, Intrauterine connectors and Maternal ECG leads.

Design, development and distribution of software relating to Vital Signs and Fetal monitors.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.