

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Deltex Medical Limited
Terminus Road
Chichester
PO19 8TX
United Kingdom

Facility ID Number: F003426

Holds Certificate No: **MDSAP 703759**

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

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

The design, development, manufacture, repair, modification, sales and distribution of Doppler ultrasound technology, haemodynamic monitors, sterile and clinically clean probes, and accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-02-20

Effective Date: 2023-02-20

Expiry Date: 2026-02-19



BSI Group America Inc. is an MDSAP recognised auditing organization

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