

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: SLE Limited
Unit 7/8, Commerce Park
Commerce Way
Croydon
CR0 4YL
United Kingdom

Facility ID Number: F006480

Holds Certificate No: **MDSAP 778948**

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

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

Design, development, manufacture and distribution of sterile and non-sterile devices associated with invasive and noninvasive respiratory support: gas flow sensors, intensive care ventilators, CPAP devices, medical gas blenders, breathing circuits, respiratory humidifiers and associated accessories. Service and distribution of devices associated with infusion therapy, respiratory support, thermoregulation, phototherapy and monitoring of vital physiological parameters.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-01-11

Effective Date: 2024-12-10

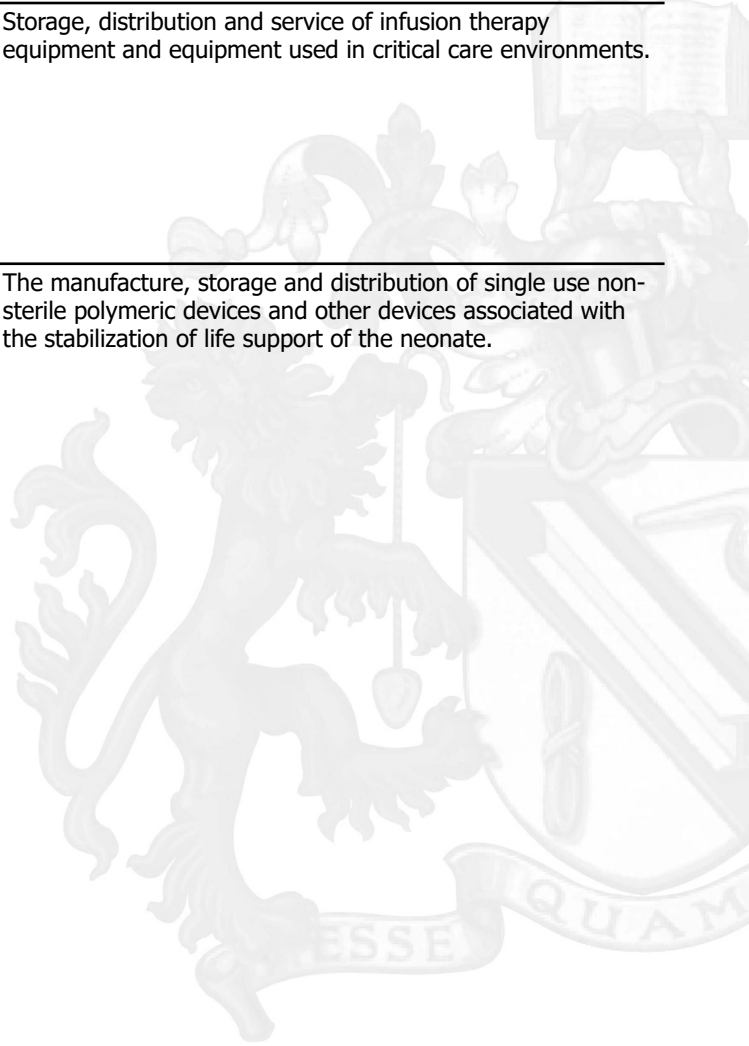
Expiry Date: 2026-11-30



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 778948**

Location	Registered Activities
SLE Limited Commerce Park Commerce Way Croydon CR0 4YL United Kingdom Facility ID Number: F006480	Design, development, manufacture and distribution of sterile and non-sterile devices associated with invasive and noninvasive respiratory support: gas flow sensors, intensive care ventilators, CPAP devices, medical gas blenders, breathing circuits, respiratory humidifiers and associated accessories. Service and distribution of devices associated with infusion therapy, respiratory support, thermoregulation, phototherapy and monitoring of vital physiological parameters.
Inspiration Healthcare Ltd Commerce Park Commerce Way Croydon Surrey CR0 4YL United Kingdom Facility ID Number: F006480	Storage, distribution and service of infusion therapy equipment and equipment used in critical care environments.
Viomedex Limited Commerce Park Commerce Way Croydon CR0 4YL United Kingdom Facility ID Number: F006480	The manufacture, storage and distribution of single use non-sterile polymeric devices and other devices associated with the stabilization of life support of the neonate.



Original Registration Date: 2024-01-11 Effective Date: 2024-12-10 Expiry Date: 2026-11-30

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