

Certificate of Registration

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

This is to certify that:

SLE Limited
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey
CR2 6PL
United Kingdom

Holds Certificate Number:

MD 689407

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

Please see scope page.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-01-16

Latest Revision Date: 2019-12-10

Effective Date: 2020-04-09

Expiry Date: 2023-04-08

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Certificate No: **MD 689407**

Registered Scope:

Design, manufacture, service, sales and distribution of Lung Ventilator and CPAP Drivers, nCPAP Generator and nasal prongs and masks, Patient breathing circuits, Nitric Oxide circuit adapter kits, Reusable EEG surface electrodes and sterile and non-sterile flow sensors and cable, Pulse Oximeter Module for use with SLE6000 Lung ventilator.

Distribution of Respiratory humidifiers, humidifier chambers and humidifier electrical adaptors for use with heated patient breathing circuits, Medical air compressors, Patient breathing circuits, Bacterial filters, Patient physiological monitoring systems and sensors, Infant incubator and transport incubator systems, Infant resuscitation systems, Patient interfaces for ventilation, Patient interface securement and skin barrier devices, Medical gas blenders, Ventilator test and gas flow analysis systems, Medical device transport trolleys, medical rail mounted patient circuit arms and drip poles, Aerosol drug delivery systems, Inhaled Nitric oxide delivery and monitoring devices, and airway suction devices.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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