By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 688636**

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

In respect of:

Design and manufacture of lung ventilators, CPAP drivers, nCPAP generator and accessories for infant and paediatric use, sterile single use and non-sterile reusable flow sensors for patient breathing circuits, reusable heated patient breathing circuits, INOSYS nitric oxide circuit adapter kits and pulse oximeter module.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2019-01-31** Date: **2019-02-18** Expiry Date: **2022-04-08**

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Number	Device Name	Intended purpose per IFU
Class IIb		
14361	Lung ventilator	Intended to provide continuous or intermittent respiratory support for premature neonates greater than 0.4kg, term neonates, infants and paediatric patients up to 20kg depending on condition.
14361	Lung ventilator	Intended to provide continuous or intermittent respiratory support for premature neonates greater than 0.3kg, term neonates and infants, as well as paediatric patients up to 30kg depending on condition.
36554	Pulse oximeter module	The SLE6000 uSpO2 Cable (Masimo SET) is indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor). The SLE uSpO2 Pulse Oximetry Cable (Masimo SET) is indicated for use with neonatal, infant and paediatric patients up to 30kg during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

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Class IIa		
MD 1102, MDS 7004	Neonatal CPAP unit	---
MD 0101	CPAP nasal oxygen cannula	---
MD 0101	Ventilator breathing circuit, reusable	---
MD 0101	Ventilator breathing circuit, single-use	---
MD 0101, MDS 7006	Breathing circuit gas-flow sensor, single use (sterile)	---
MD 0101	Breathing circuit gas-flow sensor, reusable	---

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