

EC Certificate - Full Quality Assurance System

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

No.**CE 688636****Issued To:**

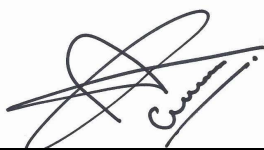
**SLE Limited
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey
CR2 6PL
United Kingdom**

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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Supplementary Information to CE 688636

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

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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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