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 for Neonatal, infant and paediatric use, nCPAP generator and accessories for infant and paediatric use, sterile single use and non-sterile reusable flow sensors for patient breathing circuits, single use and reusable ventilator breathing circuits 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-01-31** Date: **2020-02-05** Expiry Date: **2024-05-26**

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

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

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
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| Certificate No: | **CE 688636** |
| Date: | **2020-02-05** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Advena Limited<br>Tower Business Centre<br>2nd Floor<br>Tower Street<br>SWATAR BKR<br>4013<br>Malta | **EU Representative** |
| Europlaz Technologies Ltd<br>The Maltings Industrial Estate<br>Hall Road<br>Southminster<br>Essex<br>CM0 7EQ<br>United Kingdom | **Manufacture** |
| Sterigenics UK Limited<br>Seymour Link Road<br>Woodthorpe, Mastin Moor<br>Chesterfield<br>S43 3FG<br>United Kingdom | **Gamma Sterilization** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Synergy Health Stetrilisation UK Ltd<br>Marcus Close<br>Tilehurst<br>Reading<br>Berkshire<br>RG30 4EA<br>United Kingdom | **Gamma Sterilization** |
| Viomedex Ltd<br>Unit 13, Swan Barn Business Centre<br>Old Swan Lane<br>Hailsham<br>East Sussex<br>BN27 2BY<br>United Kingdom | **Manufacture** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 688636**
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| Date | Reference Number | Action |
|---|---|---|
| 31 January 2019 | 8890265 | Initial issue. Transfer from another Notified Body. |
| 18 February 2019 | 9735371 | Traceable to NB 0086. |
| Current | 3043544 | Certificate renewal. Addition of EU representative (Advena) and gamma sterilisation subcontractor (Sterigenics) to certificate critical subcontractors list.<br>Extension to scope for lung ventilator to include Neonates greater than 0.3 kg.<br>Reduction in scope to remove the CPAP drivers.<br>Change in scope wording replacing "INOSYS nitric oxide circuit adaptor kit" with "reusable ventilator breathing circuits". |