By Royal Charter

# EC Certificate - Full Quality Assurance System

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

**No.** **CE 01723**

Issued To: **Respironics Novametrix, LLC**
**2271 Cosmos Court**
**Carlsbad**
**California**
**92011**
**USA**

In respect of:

**The design, development and manufacture of monitors for cardiac output, respiratory mechanics, CO2, and pulse oximetry; including the associated sensors, masks, nasal cannulas and airway adapters used with these medical devices.**

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: **1997-09-15** Date: **2021-05-21** Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 01723**

Issued To:

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**2271 Cosmos Court**
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| Number | Device Description | Intended purpose |
|---|---|---|
| **Class IIb** | | |
| GMDN 36552<br>NBOG MD 1302 | Capnostat and LoFlo Modules and Sensors | Carbon Dioxide Monitoring |
| **Class IIa** | | |
| NBOG MD 0101 | CO2/Flow sensors | N/A for IIa devices |
| NBOG MD 0101 | Airway adaptors | N/A for IIa devices |
| NBOG MD 0101 | Cannulas and tubing for CO2 sampling and O2 delivery | N/A for IIa devices |

First Issued: **1997-09-15** Date: **2021-05-21** Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System

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:

| | |
|---|---|
| Certificate No: | **CE 01723** |
| Date: | **2021-05-21** |
| Issued To: | **Respironics Novametrix, LLC**<br>**2271 Cosmos Court**<br>**Carlsbad**<br>**California**<br>**92011**<br>**USA** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Jiangyin SINBON Electronics Co., Ltd.<br>No. 288 Chengjiang Middle Road<br>Economic and Development Zone<br>Jiangyin City<br>Jiangsu Province, 214434<br>P.R. China | **Manufacture** |
| NextPhase Medical Devices LLC.<br>Andador Vecinal No. 14301<br>Zona Cerril General<br>Tijuana, Baja California<br>CP 22330<br>Mexico | **Manufacture** |
| Philips Medizin Systeme<br>Böblingen GmbH<br>Hewlett-Packard Strasse 2<br>D-71034 Böblingen<br>Germany | **EU Representative** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Respironics Deutschland<br>GmbH & Co. KG<br>Gewerbestrasse 17<br>82211<br>Herrsching<br>Germany | **EU Representative** |
| Respironics Medical Products (Shenzhen) Co., Ltd.<br>Block 6 & 7<br>No. 129, 2nd Industrial Avenue<br>Tang Xia Yong Village, Yan Luo<br>Sub-district, Bao An District<br>518105 Shenzhen Guangdong<br>China | **Manufacture** |
| Sanmina-SCI India Pvt. Ltd.<br>OZ-1, SIPCOT HI-TECH SEZ, Oragadam<br>Sriperumpudur Taluk<br>Chennai<br>Tamil Nadu<br>602 105<br>India | **Crucial Supplier** |

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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Sanmina-SCI Systems<br>Singapore Pte Ltd<br>2 Chai Chee Drive<br>Singapore 469044<br>Singapore | **Manufacture** |
| Volcano Corporation<br>VOLCARICA S.R.L.<br>Coyol Free Zone & Business Park,B37<br>Alajuela<br>Costa Rica | **Manufacture** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01723**

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| Date | Reference Number | Action |
|---|---|---|
| 15 September 1997 | | First Issue to Novametrix Medical Systems Inc for the design, development and manufacture of pulse oximetry, capnography and pulmonary mechanics patient monitoring devices and non-sterile sensors. |
| 20 January 1999 | | Reissued to include sterile sensors in the scope. |
| 08 June 2000 | | Reissued with a change of address. Also the scope was changed by the addition of cardiac output patient monitoring devices and the removal of sterile sensors. |
| 19 July 2002 | | Renewal of certificate following five year review and a change of manufacture name to Respironics Novametrix |
| 23 June 2005 | | Reissue of certificate due to changes to manufacturers name (Inc to LLC) and address. Removal of 'development' from scope to comply with new certificate format. Certificate issued in new format. |
| 21 May 2007 | | Certificate renewal. |
| 22 December 2009 | 7464871 | Certificate re-issue due to the scope extension to include oxygen analysers, oxygen flow generators and CPAP valves. Also, clarification of existing scope. Addition of two sub-contractors, Pressco Ltd for manufacture of O2 flow generators and Respironics (HK) Ltd for manufacture of CPAP valves and of the EU Representative. |

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|---|---|---|
| 29 November 2011 | 7767333 | Reissue due to removal of Respironics (HK) Limited and addition of Respironics Medical Products (SZ) Co., Ltd. and Sanmina-SCI Systems as subcontractors.<br>Scope extension to include nasal cannulas and airway adapters. |
| 27 June 2012 | 7845052 | Certificate Renewal. |
| 28 June 2017 | 8716984 | Certificate renewal. Change to scope to remove transcutaneous monitors and amend scope for oxygen analyzers. Additional subcontractor, Sanmina-SCI India and additional EU Rep, Philips Medizin Systeme for new product ranges whilst retaining present EU Rep for legacy devices. |
| 13 February 2019 | 9659613 | Reissue to amend EU Rep name to Respironics Deutschland GmbH & Co. KG and minor adjustments to legal manufacturer's name.<br>Removal of two subcontractors, Pressco Ltd and Sanmina-SCI Systems Singapore Pte. Ltd. Addition of subcontract manufacturer Jiangyin SINBON Electronics Co., Ltd. |
| 05 March 2019 | 7781670 | Traceable to NB 0086. |

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| Date | Reference Number | Action |
|---|---|---|
| 28 October 2020 | 3205146 | Certificate re-issue with scope change. Oxygen generators, CPAP valves and aspects concerned with metrological requirements are being removed from the current scope.<br>Addition of three subcontractors<br>Volcano Corporation VOLCARICA S.R.L. for the manufacture of sensors and reusable airway adapters.<br>NextPhase Medical Devices, LLC for the manufacture Consumable nasal cannulas and airway adapters (LoFlo and CapnoTrak accessories).<br>Sanmina-SCI Systems Singapore Pte. Ltd. For the manufacture of Respiratory Mechanics.<br>Sanmina-SCI India Pvt Ltd is being moved from crtitical subcontractor to crucial supplier.<br>Addition of the word (Shenzhen) to Subcontractor Respironics Medical Products<br>Addition of device table. |
| 27 April 2021 | 3387846 | Re-issue with a change of address. The LM location has changed from '5 Technology Drive, Wallingford, Connecticut, 06492, USA' to '2271 Cosmos Court, Carlsbad, California, 92011, USA'. |
| Current | 3387637 | Certificate renewal. |