By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 669121**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

In respect of:

See certificate scope page.

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: **2017-07-20** Date: **2021-03-12** Expiry Date: **2023-03-18**

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Certificate No: CE 669121

Certificate Scope:

The design, development and manufacture of:

- **Sterile Disposable infusion kits including cassette, tubes, connectors, needles**
- **Patient warming units**
- **Blood and Fluid Warmers units**
- **Sterile Blood and Fluid Warmers disposables sets**
- **Sterile Implantable Access Systems**
- **Sterile and non-sterile vital sign monitoring probes**
- **Syringe Infusion Pumps for hospital use**
- **Volumetric Infusion pumps for hospital use**
- **Peristaltic Infusion pumps for hospital and home use**
- **Infusion Application Software**
- **Sterile Needles and Introducer for Implantable Access**
- **Sterile Blood Sampling Devices**
- **Respiratory Therapy Devices and Positive airway pressure therapy systems**
- **Positive expiratory pressure therapy systems**
- **Sterile Catheter Connectors, Loss of Resistance Devices Syringes, Epidural Filters, Epidural Needles, Hypodermic Needles and Introducer Needles**
- **Sterile Spinal and combined spinal/epidural needles**
- **Sterile and non-sterile Breathing Systems and Circuits including**
  - **Sterile and non-sterile Applications for patient Intubation**
  - **Sterile Tracheostomy Tubes, Cannulae and Kits**
  - **Sterile and non-sterile Oxygen and Humidity Management Devices,**
  - **Non-Sterile Resuscitation devices,**
  - **Non-Sterile Filtration Devices for Breathing Circuits,**
  - **Sterile and non-Sterile tracheostomy accessories**
- **Sterile Disposable Pressure Monitoring tubes, connectors and transducers**
- **Sterile Drainage Devices**
- **Sterile Suction Catheters**
- **Sterile Vascular Access Devices**
- **Sterile Peripheral Intravenous Catheters**
- **Gas Powered Emergency and Transport Ventilators**
- **Gas Powered Emergency and Transport Resuscitators**
- **Sterile Temperature sensor containing Foley Catheters**

First Issued: **2017-07-20** Date: **2021-03-12** Expiry Date: **2023-03-18**

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Supplementary Information to CE 669121

Issued To:

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NBOG code(s)	Device description	Intended purpose
Class III		
NBOG code(s)	Device (generic device name/group)	Annex II.4 CE Certificate:
MD0201	Port-a-Cath Implantable Access Systems	See CE 669193
MD0102	Cardiothoracic Catheters	See CE 683526
MD0101	Spinal Needles and combined spinal/epidural needles	See CE 685113

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD1302	Sterile and non-sterile vital sign monitoring probes	Intended for continuous temperature monitoring
MD1403	Patient warming units	Intended to prevent and treat hypothermia when temperature therapy is clinically indicated.
MD1403	Blood and fluid warmers units	Warming recirculating solution sealed in heat exchanger to warm I.V. fluid and/or blood products
MD1111	Infusion Application Software	Provide medications libraries which can be setup and stored on hospital servers
MD0101	Sterile Tracheostomy Tubes, Cannulae and Kits	create and controlled percutaneous dilational tracheostomy for tracheal access for airway management

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD1302	Sterile Temperature sensor containing Foley Catheters	Intended for temperature monitoring in patients who are catheterized
MD1102	Gas Powered Emergency and Transport Ventilators	intended for ventilation in emergency, intra & inter-hospital medical transport situations
MD1102	Gas Powered Emergency and Transport Resuscitators	intended for resuscitation in emergency, intra & inter-hospital medical transport situations

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NBOG code(s)	Device description	Intended purpose
Class IIb		
MD0102	Sterile Peripheral Intravenous Catheters	Intended for intravenous administration of medicines
MD1101	Syringe Infusion Pumps for hospital use	Intended for therapies that require various type of rate and or bolus, and/or patient-clinician controlled demand doses
MD1101	Volumetric Infusion pumps for hospital use	Intended for therapies that require various type of rate and or bolus, and/or patient-clinician controlled demand doses
MD1101	Peristaltic Infusion pumps for hospital and home use	Intended for therapies that require various type of rate and or bolus, and/or patient-clinician controlled demand doses

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NBOG code(s)	Device description	Intended purpose
Class IIa		
NBOG code(s)	Device subcategory	NA for class IIa devices
MD0101	Sterile Catheter Connectors, Loss of Resistance Devices Syringes, Epidural Filters Epidural Needles, Hypodermic Needles and Introducer Needles	NA
MD0102	Sterile Blood Sampling Devices	NA
MD0101	Sterile Respiratory Therapy Devices and positive airway pressure therapy	NA
MD0101	Sterile Positive expiratory pressure therapy systems	NA
MD0101	Sterile and non-sterile Applications for Patient Intubation	NA
MD0101	Sterile and non-Sterile Breathing Systems and circuits	NA
MD0101	Sterile Disposable Pressure Monitoring tubes, connectors and transducers	NA
MD0101	Sterile and Non-Sterile tracheostomy accessories	NA
MD0101	Sterile Tracheostomy Tubes, Cannulae and Kits	NA

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NBOG code(s)	Device description	Intended purpose
Class IIa		
NBOG code(s)	Device subcategory	NA for class IIa devices
MD0101	Sterile Suction Catheters	NA
MD0101	Sterile and non-sterile Oxygen and Humidity Management Devices	NA
MD0101	Non-Sterile Filtration Devices for Breathing Circuits	NA
MD0101	Sterile Drainage Devices	NA
MD0101	Non-Sterile Resuscitation	NA
MD1302	Sterile and non-sterile vital sign monitoring probes	NA
MD0102	Sterile Needles and Introducer for Implantable Access System	NA
MD0102	Sterile Blood and Fluid Warmers disposables sets	NA
MD0102	Sterile Disposable infusion kits including cassette, tubes, connectors, needles	NA

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Date	Reference Number	Action
20 July 2017	8691798	First issue, transferred from another notified body.
09 May 2018	8893340	Renewal, scope rewording, scope reduction, subcontractor removal, correction of subcontractor address and activities.
09 August 2018	9626931	Scope change: addition of Sterile and non-sterile vital sign monitoring probes, Infusion Pumps for hospital use, Infusion Application Software, Sterile Needles and Introducer for Implantable Access.
09 October 2018	9653527	Scope extension for Infusion pumps for home use, addition of "LVP Administration Sets" products, addition of subcontractor Kawasumi, Siam Steri Services and Synergy Health (Thailand). Correction of subcontractor address and update of subcontractor name.
22 March 2019	8784109	Traceable to NB 0086.
21 June 2019	9630479	**Addition of scope expressions:** Sterile Blood Sampling Devices, Sterile Respiratory Therapy Devices and Positive airway pressure therapy systems, Sterile Positive expiratory pressure therapy systems, Sterile Catheter Connectors, Loss of Resistance Devices Syringes, Epidural Filters, Epidural Needles, Hypodermic Needles and Introducer Needles, Sterile Spinal and combined spinal/epidural needles including correct inject spinal needles Devices, Sterile and non-sterile Breathing Systems and Circuits including, -Sterile and non-sterile Applications for patient Intubation, -Sterile Tracheostomy Tubes and Kits (-Sterile and non-sterile Oxygen and Humidity Management, - Non-Sterile Resuscitation devices, -Non-Sterile Filtration Devices for Breathing Circuits, -And Sterile and Non-Sterile tracheostomy accessories Sterile Disposable Pressure Monitoring tubes, connectors and transducers), Sterile Drainage Devices, Sterile Suction Catheters, Sterile Cardiothoracic Catheters

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Date	Reference Number	Action
21 June 2019	9630479	**Removal of scope expression:** Those aspects of Annex II concerned with securing and maintaining sterile conditions of convective warmers blankets. **Addition of subcontractors:** Smiths Medical ASD Keene, Dublin, Southington, Smiths Medical North America Olive Branch, Smiths Medical Deutschland GmbH Fraureuth, Smiths Medical International Cumbernauld, Smiths Medical Nederland BV Bijsterhuizen, Smiths Medical Czech Republic a.s. Hranice, Smiths Medical Italia S.r.l Latina, Smiths Healthcare Manufacturing SA de CV Monterrey, Smiths Medical ASD Inc, Gary, B. Braun Medical Ltd, Becton, Dickinson and Compnay, BD Medical Surgical Systems, Becton, Dickinson GmbH, Brightwake Ltd, Galemed Corporation, GE Medical, HA2 Medizintechnik GmbH, Innovative Medical Manufacturing Company, Isomedix Operations, Inc. Northborough, Martech Medical Products, Inc., Medisize CZ s.r.o., Nipro (Thailand) Corporation Limited, PAJUNK GmbH Medizintechnologie , Pall Medical-A Division of Pall International Sàrl, Plastibell Mar-Lee USA, Sovrin Plastics Ltd, Sterigenics Belgium (Petit-Rechain) SA, Sterigenics UK Ltd Alfreton, Sterilization Services of Tennessee, Tae-Chang Industrial Co., Ltd, TOP Corporation, Unisis Corp, UPG, Velcro USA Inc., Xeridiem Medical Devices, MicroMo Electronics Inc, LISI Medical Remmele, Norautron Suzhou Co., Ltd., Plexus Corp. , Providence Enterprises Limited, OSI Optoelectronics, Inc., Smiths Medical International Limited (Luton). Removal of: Sterigenics US, LLC (Willowbrook, Ilinois), STERIS Applied Sterilization Technologie Formerly Synergy Health Applied Steriliz **Addition of the supplementary device table.**

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Date	Reference Number	Action
24 March 2020	3096113	Extension of scope to include Gas Powered Emergency and Transport Ventilators, Gas Powered Emergency and Transport Resuscitators and Sterile Temperature sensor containing Foley Catheters Addition of subcontractor - Sterilization Services of Georgia Update activity for existing subcontractor - addition of packaging to Xeridiem Medical Devices.
20 April 2020	3089597	Extension of scope to include Sterile Peripheral Intravenous Catheters, Syringe Infusion Pumps for hospital use and Volumetric Infusion pumps for hospital use. Administrative Modification of scope from "Infusion pumps for hospital and home use" to "Peristaltic Infusion pumps for hospital and home use" Addition of subcontractors - GaleMed (Xiamen) Co., Ltd., Sterilization Services of Virginia Update activity for existing subcontractor - addition of packaging to Smiths Medical ASD, Inc. (Southington, CT)
10 June 2020	3221131	Addition of significant subcontractors - GKN Aerospace Service Ltd – Cowes Site, GKN Aerospace Service Limited and Rolls Royce plc

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Date	Reference Number	Action
09 November 2020	3254778	Updated scope expression for 'Sterile Tracheostomy Tubes, Cannulae and Kits; amended class IIb product table; added scope to class IIa product table Removal of 'Sterile Peripheral Implantable Access Systems' from product table in regards to class IIb device Modified scope expression for Port-A-Cath product family by replacing 'Sterile Central Implantable Access Systems' and 'Sterile Peripheral Implantable Access Systems' with 'Sterile Implantable Access Systems' Addition of 'manufacturing' as a service supplied for Smiths Medical Italia S.R.L (Latina Italy) Addition of STERIS S.p.A (Calcinate, Italy) for EtO Sterilization Addition of Poly Medicure Limited for Manufacture and EtO sterilization Addition of Sterigenics Italy Spa Via (Bologna) for Gamma Irradiation Addition of Synergy Health AST (Netherlands) for Gamma Irradiation

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<table>
<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td>12 March 2021</td><td>3371747</td><td>Addition of sterilization subcontractor Sterigenics US, LLC.</td></tr>
<tr><td colspan="3">Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3</td></tr>
<tr><td>18 January 2022</td><td>3614637</td><td>Scope restriction to suspend Level 1® Fast Flow Fluid Warmers, Normothermic Administration Sets, and corresponding Accessories from the market. Model numbers listed below:
<table>
<tr><th>Product Model Name</th><th>Model Number</th></tr>
<tr><td>Level 1 Fluid Warmer</td><td>H-1000</td></tr>
<tr><td>Level 1 Fluid Warmer Systems</td><td>H-1000
H-1025
H-1200</td></tr>
<tr><td>Level 1 Normothermic I.V. Fluid Administration Set</td><td>D-100
D-300
D-50
D-60HL
DI-100
DI-300
DI-50
DI-60HL
D-70
DI-70</td></tr>
</table></td></tr>
</table>

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Date	Reference Number	Action

Product Model Name	Product Model Name
Pressure Chambers	7204036 7204017 7204031 7204012 7204018 7204016 7204034 7204030 7204074 7204019 7204066 7204020 7204037 7204068
High-Flow 3 Way Stopcock	SC-3
High Flow Extension Line	X-36
High Flow Extension with Injection Site	Y-INJ
Gas Vent/Filter Assembly	F-10 F-30

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<table>
<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td>28 January 2022</td><td>3620387</td><td>Scope restriction to suspend Level 1® NormoFlo® Fluid Warmers, Level 1® NormoFlo® Irrigation Fluid Warming Sets, and corresponding Accessories from the market. Model numbers listed below:
<table>
<tr><th>Product Model Name</th><th>Product Model Name</th></tr>
<tr><td>Level 1® NormoFlo® Fluid Warmer</td><td>H-1100
H-1129</td></tr>
<tr><td>Level 1® NormoFlo® Irrigation Fluid Warming Sets</td><td>IR-40
IR-500
IR-600
IRI-600
IRI-600B
IRI-700</td></tr>
<tr><td>Patient Line Sets</td><td>PL-6
PL-7</td></tr>
</table>
</td></tr>
</table>

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Date	Reference Number	Action
21 February 2022	3579227	Removal of Manufacturers GKN Aerospace Service Limited, GKN Aerospace Services Ltd – Cowes Site, Rolls Royce plc, and Smiths Medical International Limited (Kent). Addition of ETO Sterilizer, Sterigenics UK Ltd. Administrative change: The device table on page 3 refers to CE 685113 for the intended purpose of Spinal Needles and combined spinal/epidural needles. The correct reference is CE 683527.
17 March 2023	3754513	**Removal of scope expression:** • Syringe Infusion Pumps for hospital use • Volumetric Infusion pumps for hospital use • Non-sterile Resuscitation devices **Reduction in scope:** Removal of the following devices from the market: • Pleural Catheters (in "Sterile Drainage Devices" scope expression)

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Date	Reference Number	Action		
			Device Name	**Device Model**
			Portex® Pleural Catheters for Blunt Dissection	200/802/100
				200/802/120
				200/802/160
				200/802/200
				200/802/240
				200/802/280
				200/802/320
				200/802/360
			Portex® Pleural Catheter with Flexible Introducer	200/804/200
				200/804/240
				200/804/280
				200/804/320
				200/804/360
				200/806/200
				200/806/240
				200/806/280
				200/806/320
				200/806/360

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<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>

Oxygen and Aerosol Delivery (in "Sterile and non-sterile Oxygen and Humidity Management Devices" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>Portex® Nasal Oxygen Set</td><td>100/285/100</td></tr>
<tr><td>Portex® Thermovent® O2</td><td>100/575/010</td></tr>
</table>

Specialty Filter Devices (in "Non-sterile Filtration Devices for Breathing Circuits" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>Portex Suction Filter with Adapter</td><td>002531</td></tr>
<tr><td>Portex Resuscitation Exhalation Port Filter</td><td>8518</td></tr>
</table>

TheraPep Positive Expiratory Pressure Therapy System Devices (in "Positive expiratory pressure therapy systems" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>TheraPEP® Therapy System with Pediatric Mask</td><td>20-3112</td></tr>
<tr><td>Pediatric mask</td><td>20-3115</td></tr>
<tr><td>TheraPEP® Therapy System with Small Adult Mask</td><td>20-5112</td></tr>
<tr><td>Small mask</td><td>20-5115</td></tr>
<tr><td>TheraPEP® Therapy System with Large Adult Mask</td><td>20-7112</td></tr>
<tr><td>Large mask</td><td>20-7115</td></tr>
</table>

</td></tr>
</table>

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<table>
<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>

Ventilator Support Products (in "Respiratory Therapy Devices and positive airway pressure therapy systems" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>Ventlok Quick Release Swivel Adaptor</td><td>66-1997</td></tr>
<tr><td>Circuvent HME/HCH Bypass NS</td><td>68-1000</td></tr>
</table>

Breathing Masks (in "Sterile and non-sterile Breathing Systems and Circuits" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>ANAESTHETIC FACE MASK PREMIUM AIR CUSHION ADULT</td><td>5045</td></tr>
<tr><td>PREMIUM DISP. ANAES FACE MASK NEONATAL, NO HOOK RINGS</td><td>5061</td></tr>
<tr><td>ANAESTHETIC FACE MASK PREMIUM AIR CUSHION TODDLER</td><td>5070</td></tr>
<tr><td>ANAESTHETIC FACE MASK PREMIUM AIR CUSHION 15MM NEONATAL</td><td>5071</td></tr>
<tr><td>ANAESTHETIC FACE MASK PREMIUM REGULAR ADULT, DK BLUE HK RING</td><td>5245</td></tr>
<tr><td>ANAESTHESIA FACE MASK PREMIUM AIR CUSHION CLEAR CHILD</td><td>5248</td></tr>
</table>

</td></tr>
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<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>
Breathing Masks (in "Sterile and non-sterile Breathing Systems and Circuits" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>ANAESTHETIC FACE MASK PREMIUM AIR CUSHION ADULT</td><td>5255</td></tr>
<tr><td>ANAESTHESIA MASK, PREMIUM PLUSUNIV. ADLT,THUMB NOTCH,HK RING</td><td>5265</td></tr>
<tr><td>ANAESTHESIA MASK, PREMIUM PLUSUNIV. ADLT, THUMB NOTCH, HK RING 30/CA</td><td>5266</td></tr>
<tr><td>ANAESTHESIA FACE MASK PREMIUM AIR CUSHION TODDLER</td><td>5270</td></tr>
<tr><td>MASK P IN NS</td><td>5052P1</td></tr>
<tr><td>MASK P AD S HR NS</td><td>5055P1</td></tr>
</table>
</td></tr>
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<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>
• Intubation System and Endotracheal Tubes (in "Sterile and non-sterile Breathing Systems and Circuits" scope expression)
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 28FR R+</td><td>197-28R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 32FR R+</td><td>197-32R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 35FR R+</td><td>197-35R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 37FR R+</td><td>197-37R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 39FR R+</td><td>197-39R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 41FR R+</td><td>197-41R</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 28FR L+</td><td>198-28L</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 32FR L+</td><td>198-32L</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 35FR L+</td><td>198-35L</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 37FR L+</td><td>198-37L</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 39FR L+</td><td>198-39L</td></tr>
<tr><td>ENDOBRONCHIAL TUBE STR 41FR L+</td><td>198-41L</td></tr>
</table>
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Date	Reference Number	Action
		• Tracheostomy - Cricothyroidotomy Kits (in "Sterile and non-sterile Breathing Systems and Circuits" scope expression)

Device Name	Device Model
Mini-Trach II Seldinger 4.0mm Cricothyroidotomy Kit 15mm Con	100/461/000
Portex Mini-Trach II	100/462/000
Emergency Cricothyroidotomy	100/465/060CZ
Portex Emergency Surgical Cricothyrotomy Kit	942/800/0000CZ

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<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>
• Ventilator Support Products (in "Sterile and non-sterile Breathing Systems and Circuits"
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>DURALIFE SET,15MM, SGL SWVL, ELBW, NO PORT NS</td><td>60-1502</td></tr>
<tr><td>DURALIFE SET,15MM, DBL SWVL, ELBW, PORT NS</td><td>60-1510</td></tr>
<tr><td>DURALIFE CONN, DBL SWIVEL, ELBOW, PORT NS</td><td>60-0010</td></tr>
<tr><td>CONNECTOR, SWIVEL, DBL ELBOW, PORT NS</td><td>66-1991</td></tr>
<tr><td>CONNECTOR, SWIVEL, DBL ELBOW, NO PORT NS</td><td>66-1995</td></tr>
<tr><td>ULTRASET CONNECTOR, STRAIGHT NS</td><td>66-2504</td></tr>
<tr><td>ULTRASET CONNECTOR, DBL SWVL, ELBOW, PORT NS</td><td>66-2505</td></tr>
<tr><td>ULTRASET CONN, DBL SWIVEL, ELBOW, NO PORT NS</td><td>66-2509</td></tr>
<tr><td>ULTRALOK FLEX-SET TUBING, VENTLOK NS</td><td>66-2507</td></tr>
</table>
</td></tr>
</table>

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2021-03-12**

Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Date	Reference Number	Action
19 July 2023	30001593	Scope restriction to permanently remove Level 1® Fast Flow Fluid Warmers, Normothermic Administration Sets and accessories, Level 1® NormoFlo® Fluid Warmers, Level 1® NormoFlo® Irrigation Fluid Warming Sets, and corresponding accessories from the market. Model numbers listed below:

Product Model Name	Product Model Number
Level 1 Fluid Warmer	H-1000
Level 1 Fluid Warmer Systems	H-1000 H-1025 H-1200
Level 1 Normothermic I.V. Fluid Administration Set	D-100 D-300 D-50 D-60HL DI-100 DI-300 DI-50 DI-60HL D-70 DI-70

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Date	Reference Number	Action	
		Pressure Chambers	7204036 7204017 7204031 7204012 7204018 7204016 7204034 7204030 7204074 7204019 7204066 7204020 7204037 7204068
		High-Flow 3 Way Stopcock	SC-3
		High Flow Extension Line	X-36
		High Flow Extension with Injection Site	Y-INJ
		High Flow Y-Type Extension	Y-30

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Date	Reference Number	Action	
		Gas Vent/Filter Assembly	F-10 F-30
		NORMOFLO Fluid Warmer	H-1100 H-1129
		NORMOFLO Irrigation Warming Set	IR-40 IR-500 IR-600 IRI-600 IRI-600B IR-700
		Patient Line Sets	PL-6 PL-7

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<table>
<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td>09 April 2024</td><td>30093955</td><td>
Removal of scope expression:
• Non-sterile Filtration Devices for Breathing Circuits.
Reduction in scope:
Removal of the following devices from the market:
• Portex® Filtration: Specialty Filters (in "Non-sterile Filtration Devices for Breathing Circuits")
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>Portex® Filtration: Specialty Filters (S1021)</td><td>02900</td></tr>
</table>
• TheraPEP® Bronchial Hygiene Devices (in "Positive expiratory pressure therapy systems")
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>TheraPEP® Bronchial Hygiene Devices (S1096)</td><td>20-0005
20-0010
20-0022
20-0050
20-0055
20-0120
20-1110
20-1112</td></tr>
</table>
</td></tr>
</table>

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<table>
<tr><th>Date</th><th>Reference Number</th><th>Action</th></tr>
<tr><td></td><td></td><td>• Portex® Filtration: Bacterial Viral Filters (in "Non-sterile Filtration Devices for Breathing Circuits")
<table>
<tr><th>Device Name</th><th>Device Model</th></tr>
<tr><td>Portex® Filtration: Bacterial Viral Filters (S1019)</td><td>02862</td></tr>
</table></td></tr>
<tr><td>05 September 2024</td><td>30252273</td><td>Addition of manufacturing location, critical subcontractors, and crucial suppliers</td></tr>
<tr><td>01 August 2025</td><td>30433380</td><td>Change to manufacturing facility of Level 1 Hotline fluid warmers.
Change to sterilization site for Bivona tracheostomy tube.
Change of Legal Manufacturer name from Smiths Medical ASD, Inc to ICU Medical Inc.
Removal of Sterile Temperature Sensor containing Foley Catheters scope expression (Foley Catheters).
Removal of Equator Convective warmer.
Removal of CADD Legacy Duodopa.
Removal of critical subcontractors.
Change of EU Authorized Representative.</td></tr>
</table>

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

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6000 Nathan Lane North
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Date	Reference Number	Action
14 November 2025	30480810	Product certificates CE 683526 & CE 683527 removed from scope. Change in critical subcontractor for manufacturing of Arterial blood sampling products (S1257), Hypodermic Needle Pro EDGE (S1143), Hypodermic Needle Pro (S1133), EpiFuse Catheter Connector with NRFit Connector and Key (S1276/S1177), Portex Epidural Tuohy and Hustead Needles (S1276), Portex Loss of Resistance (L.O.R.) Syringe with NRFit Connector (S1276), Portex Epidural Kits (S1276 and S1177), Epifuse Catheter Connector (S1177) & Portex Epidural Single Shot Trays (S1276) devices.