

# 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****...making excellence a habit.™**

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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.

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**

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## Supplementary Information to CE 669121

Issued To:

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USA**

NBOG code(s)	Device description	Intended purpose
<b>Class III</b>		
<i>NBOG code(s)</i>	<i>Device (generic device name/group)</i>	<i>Annex II.4 CE Certificate:</i>
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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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.

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NBOG code(s)	Device description	Intended purpose
<b>Class IIb</b>		
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
<b>Class IIb</b>		
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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<b>Class IIb</b>		
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
<b>Class IIa</b>		
<i>NBOG code(s)</i>	<i>Device subcategory</i>	<i>NA for class IIa devices</i>
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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<b>Class IIa</b>		
<i>NBOG code(s)</i>	<i>Device subcategory</i>	<i>NA for class IIa devices</i>
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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