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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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-07-20** Date: **2019-06-21** Expiry Date: **2023-03-18**

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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.

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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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 Central Implantable Access Systems**
- **Sterile Peripheral Implantable Access Systems**
- **Sterile and non-sterile vital sign monitoring probes**
- **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 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**

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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:*
MD 0201	Port-a-Cath Implantable Access Systems	See CE 669193
MD 0102	Cardiothoracic Catheters	See CE 683526
MD 0101	Spinal Needles and combined spinal/epidural needles	See CE 685113
Class IIb		
NBOG code(s)	*Generic Device Group*	*Intended purpose*
MD 0101	Sterile Tracheostomy Tubes and kits	create and controlled percutaneous dilational tracheostomy for tracheal access for airway management
MD 0201	Sterile Peripheral Implantable Access Systems	indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling

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NBOG code(s)	Device description	Intended purpose
Class IIb		
NBOG code(s)	*Device (generic device name/group)*	*Annex II 4 CE Certificate:*
MD 1302	sterile and non-sterile vital sign monitoring probes	Intended for continuous temperature monitoring
MD 1403	Patient warming units	Intended to prevent and treat hypothermia when temperature therapy is clinically indicated.
MD 1403	Blood and fluid warmers units	Warming recirculating solution sealed in heat exchanger to warm I.V. fluid and/or blood products
MD 1111	Infusion Application Software	Provide medications libraries which can be setup and stored on hospital servers
MD 1101	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

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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
MD 1302	Sterile and non-sterile vital sign monitoring probes	NA
MD 0102	Sterile Needles and Introducer for Implantable Access System	NA
MD 0102	Sterile Blood and Fluid Warmers disposables sets	NA
MD 0102	Sterile Disposable infusion kits including cassette, tubes, connectors, needles	NA

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