Certificate of Registration

This is to certify that the quality management system of

SMITHS MEDICAL INTERNATIONAL LIMITED

Boundary Road, Hythe, Kent, CT21 6JL, UK

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

Design of:
Breathing Systems, Drainage Devices, Feeding Devices, Filtration Devices, Infusion Disposables, Intubation Systems, Obstetrics and Gynaecology Devices, Oxygen and Humidity Management Devices, Pressure Monitoring Devices, Respiratory Mechanics Devices, Resuscitation Devices, Suction Catheters, Tracheostomy Tubes, Vascular Access Devices, Cardio Thoracic Catheters and Drapes

Additional Site:
Human Resources and Training, Shipping, Demand Planning, Post Market Surveillance, Market Intelligence, E-Business, International Customer Services, Business Development, Registrations, Finance, Wallace Women's Healthcare

Certificate Number:	**053-01 B**
Initial Certification Date:	**20 October 2005**
Certificate Effective Date:	**23 July 2016**
Certificate Expiry Date:	**22 July 2019**

UKAS MANAGEMENT SYSTEMS
061

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd

C-Fusor® - The pressure infusor

A clear solution for Pressure Infusion, Transfusion and Flushing

- Secure fastening.
- Unique design ensures rapid set-up and fluid bag replacement.
- Accurate and easy-to-read pressure gauge.
- Crystal clear material allows maximum visibility of fluid levels.
- Allows for even pressure around the fluid container.
- Durable and easy to clean.
- Large squeeze bulb for rapid and reliable pressure control.
- Three-way stopcock prevents air leaks.
- 1000ml and 500ml sizes available.
- Extension sets available for two and three litre bags.

C-Fusor® Products (Outside US Codes)

Code	Product Codes	Qty
MX 4805P1	500ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4810P1	1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4806	C-Fusor® 500ml replacement bag only	1
MX 4830P1	Expansion set for MX 4810, 3L fluid container	1
MX 1821-B	Squeeze bulb, male luer lock and 3-way stopcock	1
MX 1821-G	Pressure guage, 0-760mm Hg	1

C-Fusor® Products (US Codes)

Code	Product Codes	Qty
MX 4805	500ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4810	1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4830	Expansion set for MX 4810, 3L fluid container	1
MX 1821-B	Squeeze bulb, male luer lock and 3-way stopcock	1
MX 1821-G	Pressure guage, 0-760mm Hg	1

For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

Smiths Medical
1500 Eureka Park, Ashford, Kent, TN25 4BF, UK
Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761

www.smiths-medical.com
Smiths Medical, part of the global technology business Smiths Group

Literature No. LIT/PV3124 10/2010

smiths medical

smiths medical
bringing technology to life

C-Fusor®
The pressure infusor

PRESSURE MONITORING

medex™

smiths

PRESSURE INFUSOR

C-Fusor®

the pressure infusor



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- Extension sets available for two and three litre bags.

C-Fusor® Products

Article	Description	Qty
MX 4805	500ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4810	1000ml unit, complete with manometer, squeeze bulb and 3-way stopcock	1
MX 4806	C-Fusor® 500ml replacement bag only	1
MX 4811	C-Fusor® 1000ml replacement bag only	1
MX 4830	Expansion set for MX 4810, 3L fluid container	1
MX 1821-B	Squeeze bulb, male luer lock and 3-way stopcock	1
MX 1821-G	Pressure gauge, 0-760mm Hg	1

For further information please call your local Smiths Medical distributor or Smiths Medical on +44 (0)1303 260551

smiths

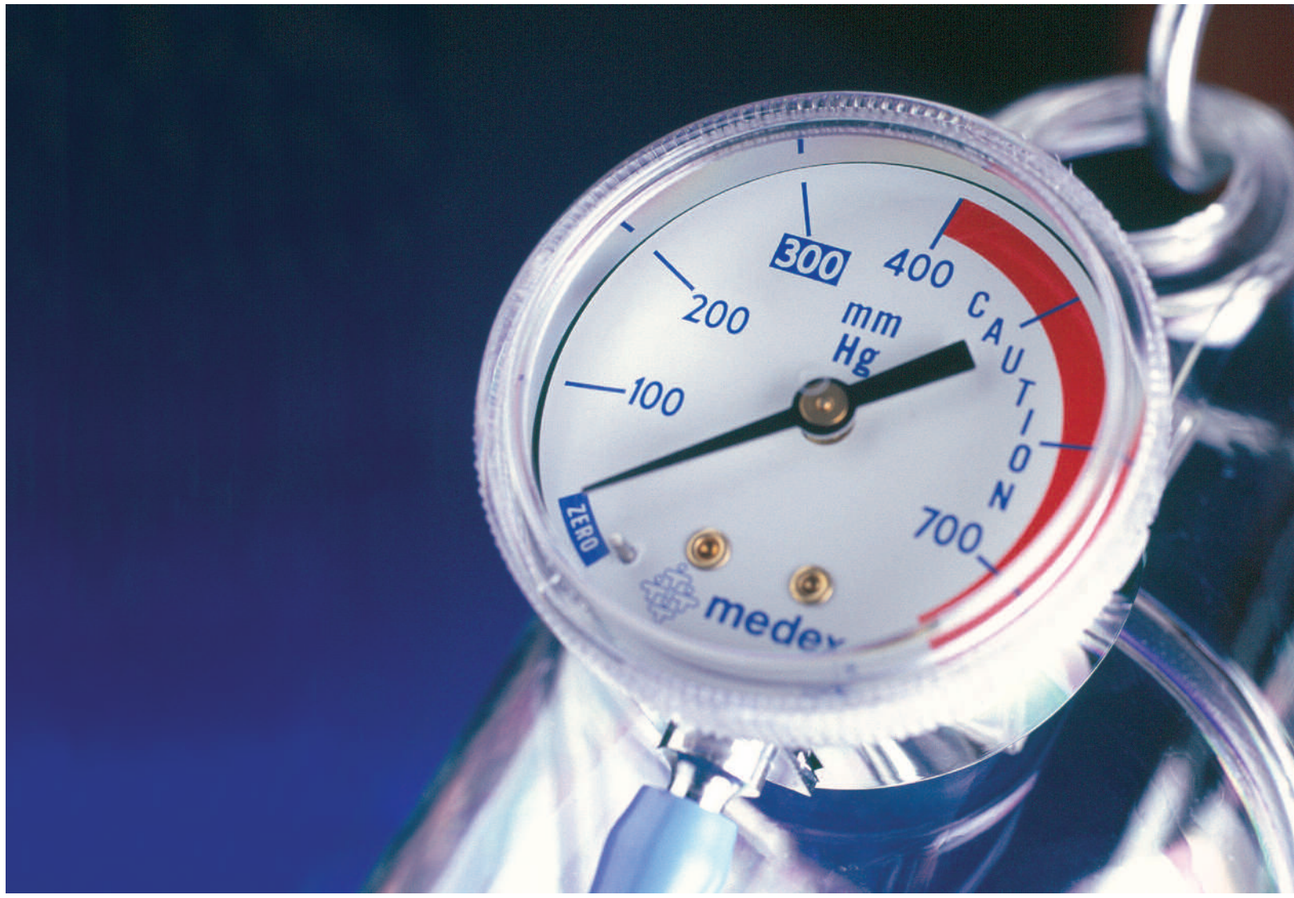
Smiths Medical International Ltd

Hythe, Kent CT21 6JL UK
Tel: +44 (0)1303 260551 Fax: +44 (0)1303 266761
www.smiths-medical.com

Literature No. LIT/PV2590

smiths

Smiths Medical - a part of Smiths Group plc



PRESSUREMONITORING

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: **2019-06-21** Expiry Date: **2023-03-18**

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By Royal Charter

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**

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

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 669121

Issued To:

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

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

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

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Supplementary Information to CE 669121

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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

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

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 669121

Issued To:

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6000 Nathan Lane North
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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

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

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6000 Nathan Lane North
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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

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

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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:

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Date:	**2019-06-21**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
B. Braun Medical Ltd Thorncliffe Park Sheffield S35 2PW United Kingdom	**Manufacture**
Becton Dickinson GmbH Tullastr. 8 - 12 Heidelberg 69126 Germany	**Manufacture**
Becton, Dickinson and Company BD Medical Surgical Systems 1 Becton Drive Franklin Lakes, NJ 07417 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Brightwake Limited Lowmoor Business Park, Kirkby in Ashfield, Nottinghamshire, NG17 7JZ, UK	**Manufacture**
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia I-Lan 268 Taiwan	**Manufacture**
GE Medical Systems Limited Pollards Wood Nightingales Lane Chalfont St Giles HP8 4SP United Kingdom	**Manufacture**

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Subcontractor:	**Service(s) supplied**
HA2 Medizintechnik GmbH Tschaikowskistraße 2 38820 Halberstadt Germany	**ETO Sterilization**
Innovative Medical Manufacturing Company No.107 LN. 181, Sec. 1, Yongzhen Rd., Zhunan Township Miaoli County 35057 Taiwan (R.O.C)	**Manufacture**
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	**Gamma Sterilization**

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

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis MN 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 43425 Business Park Drive Temeluca California 92590 USA	**ETO Sterilization**
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	**ETO Sterilization**

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

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Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**ETO Sterilization**
Kawasumi Laboratories (Thailand) Co., Ltd, Nava Nakorn Industrial Promotion Zone, 55/26 MU,13, Phahon Yothin Road, KM-46, Tambon Khlong Nueng Amphoe Khlong Luang, Changwat Pathum Thani 12120, Thailand	**Manufacture**
Koo Medical Equipment (Shanghai) Co., Ltd. 100 Zhongde Road, Xiaokunshan Town, Songjiang, Shanghai 201614, P.R. China	**Manufacture**

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Subcontractor:	**Service(s) supplied**
LISI Medical Remmele 441 93rd Avenue NW Coon Rapids Minnesota 55443 USA	**Manufacture**
Martech Medical Products, Inc. 1500 Delp Drive Harleysville PA 19438 United State of America	**Manufacture**
Medisize CZ s.r.o. Tovární 560 374 15 Trhové Sviny Czech Republic	**Manufacture**

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Subcontractor:	**Service(s) supplied**
MicroMo Electronics Inc 14881 Evergreen Avenue Clearwater FL 33762 USA	**Manufacture**
Minnetronix, Inc. 1635 Energy Park Drive St. Paul MN 55108 USA	**Design** **Manufacture**
Nipro (Thailand) Corporation Limited 10/2 Moo 8 Bangnomko, Sena Phra Nakhon Si Ayutthaya 13110 Thailand	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Norautron Suzhou Co., Ltd. Building #35, #40 and #6 Dong Jing Industrial Square, SIP, Suzhou, Jiangsu, China	**Manufacture**
OSI Optoelectronics, Inc. 12525 Chardon Avenue Hawthrone CA 90250 USA	**Manufacture**
PAJUNK GmbH Medizintechnologie Karl-Hall-Strasse 1 78187 Geisingen Germany	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Pall Medical-A Division of Pall International Sarl Avenue de Tivoli 3 1700 Fribourg, Switzerland	**Manufacture**
Plastibell Mar-Lee USA 180 Authority Drive Fitchburg, MA 01420 United State of America	**Manufacture**
Plexus Corp. 2444 Schultz Drive, Nennah, WI 54956 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Providence Enterprises Limited No. 5-4 Neihuan Road, Shanxia Village, Pinghu, Shenzhen, P.R. China	**Manufacture**
Siam Steri Services Co.,Ltd. 700/644 Amata Nakorn Industrial Estate Moo 3, Tambol bankao Amphur Panthong Chonburi 20160 Thailand	**ETO Sterilization** **Gamma Irradiation**
Smiths Healthcare Manufacturing S.A. de C.V. Avenida Calidad No. 4, Industrial Internacional Tijuana, Tijuana, B.C. C.P. 22425 Mexico	**Manufacture**

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

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

Subcontractor:	**Service(s) supplied**
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	**Manufacture**
Smiths Medical ASD Inc. 5700 West 23rd Avenue Gary IN 46406 USA	**Manufacture**
Smiths Medical ASD, Inc 6000 Nathan Lane North Minneapolis Minnesota 55442 USA	**Design** **Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Smiths Medical ASD, Inc 10 Bowman Drive Keene New Hamphshire 03431 USA	**Manufacture**
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	**Manufacture**
Smiths Medical ASD, Inc. 6250 Shier Rings Road, Dublin, OH, 43016, United States	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Smiths Medical ASD, Inc. 201 West Queen Street, Southington, CT, 06489 United States	**Manufacture**
Smiths Medical Czech Republic a.s. Olomoucká 306 753 01 Hranice Czech Republic	**EU Representative** **Manufacture**
Smiths Medical Deutschland GmbH Werdauer Strasse 51 D-08427 Fraureuth Germany	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF UK	**Manufacture**
Smiths Medical International Limited Bramingham Business Park, Enterprise Way, Luton, Beds, LU3 4BU, United Kingdom	**Manufacture**

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

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Subcontractor:	**Service(s) supplied**
Smiths Medical International Ltd 52 Grayshill Road Westfield Industrial Estate Cumbernauld Glasgow G68 9HQ United Kingdom	**Manufacture**
Smiths Medical Italia S.r.l Via della Stazione 2 Latina Scalo Latina 04100 Italy	**Packaging**
Smiths Medical Nederland BV Smiths Medical International Bijsterhuizen 22 - 08 6604 LD Wijchen, The Netherlands	**Final Inspection**

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

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Subcontractor:	**Service(s) supplied**
Smiths Medical North America 9124 Polk Lane Olive Branch Mississipi 38654 USA	**Final Inspection**
Sovrin Plastics Ltd Stirling Road Slough Berkshire SL1 4ST United Kingdom	**Manufacture**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers, Liege B-4800 Belgium	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton, DE55 4NJ United Kingdom	**ETO Sterilization**
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	**ETO Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Gamma Sterilization**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	**Gamma Sterilization**
Sterilization Services of Tennessee 2396 Florida Street Memphis Tennessee 38109 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Tae-Chang Industrial Co., Ltd (Gongju Plant) 8-18, Bojeokdong-gil Useong-myeon, Gongju-si, Chungcheongnam-do Korea	**Manufacture**
Teleflex Medical Wire Products, Inc. Telefelx Medical OEM Division 6550 Wedgwood Road North Suite 300 Maple Grove Minnesota 55311 USA	**Manufacture**
TOP Corporation 19-10 Senju Nakai-cho Adachi-ku, Tokyo 120-0035 Japan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
UNISIS CORP. Saitama Plant 2675-1 Nishikata Koshigaya-shi Saitama 343-0822 Japan	**Manufacture**
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	**Manufacture**

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

Certificate No:	**CE 669121**
Date:	**2019-06-21**
Issued To:	**Smiths Medical ASD Inc.** **6000 Nathan Lane North** **Minneapolis** **Minnesota** **55442** **USA**

Subcontractor:	**Service(s) supplied**
Velcro USA Inc. 95 Sundial Avenue, Manchester, New Hampshire 03103-7206 USA	**Crucial Supplier**
Xeridiem Medical Devices 4700 South Overland Drive Tucson, AZ 85714-3430 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2019-06-21**

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

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**
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USA

22 March 2019	8784109	Traceable to NB 0086.
Current	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 **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

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669121**

Date: **2019-06-21**

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

		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.**

Certificat de Înregistrare

Intertek

Se certifică prin prezenta că sistemul de management al calității al

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Republica Cehă

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru:

Proiectarea, asamblarea, fabricarea, ambalarea și furnizarea de:

Dispozitive și Accesorii pentru Obstetrică și Ginecologie,
Dispozitive și Accesorii Intervenție Imagistică,
Dispozitive de Management al Oxigenului și Umidității,
Dispozitive și Accesorii de Management al Durerii,
Dispozitive și Accesorii Invazive de Monitorizare a Tensiunii Pacientului,
Dispozitive Traheotomie,
Dispozitive de Unică Folosință pentru Injecții,
Dispozitive Catetere Aspirare,
Sisteme de Dispozitive de Intubare.

Certificat Număr: **1201-04 B**
Data Inițială a Certificării: **10 Ianuarie, 2014**
Data Efectivă a Certificatului: **22 Mai 2017**
Data Expirării Certificatului: **28 Februarie 2019**

UKAS MANUFACTURING 9751/05

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
Acest Certificat este proprietatea AMTAC Certification Services Ltd

****

Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

Traducător autorizat
Nr. 2769/2015

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
TRADUCĂTOR AUTORIZAT

Certificat de Înregistrare

Intertek

Prin prezenta se certifică faptul că sistemul de management al calității al

SMITHS MEDICAL INTERNATIONAL LIMITED

Boundary Road, Hythe, Kent, CT21 6JL, UK

a fost evaluat și înregistrat de AMTAC Certification Services Limited ca fiind conform cerințelor:

EN ISO 13485:2012

Sistemul de management al calității este aplicabil pentru:

Proiectarea:
Sistemelor de Respirat, Dispozitivelor de Drenaj, Dispozitivelor de Alimentare, Dispozitivelor de Filtrare, Infuzoare de Unică Folosință, Sisteme de Intubare, Dispozitive de Obstetrică și Ginecologie, Dispozitive de Management al Oxigenului și Umidității, Dispozitive de Monitorizare a Presiunii, Dispozitive Mecanice de Respirație, Dispozitive de Resuscitare, Catetere Sucțiune, Tuburi Traheotomie, Dispozitive Acces Vascular, Catetere Cardio Toracice și Comprese Chirurgicale

Poziții Suplimentare:
Resurse Umane și Pregătire Profesională, Transport, Cerere Planificare, Supraveghere Post Piață, Cunoașterea Pieței, E-Business, Servicii Client Internațional, Dezvolatre Afacere, Înregistrări, Finanțe, Wallace Women's Healthcare

Certificat Număr: Inițial Data **053-01 B**
Certificării: Dată Efectivă **20 Octombrie 2005**
Certificat: **23 Iulie 2016**
Data Expirării Certificatului: **22 Iulie 2019**

UKAS MANAGEMENT SYSTEMS
061

Brian Johnson

AMTAC Certification Services Limited, Milton Keynes, UK
Acest certificat este proprietatea AMTAC Certification Services Ltd

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Atestat nr. 2769
TRADUCĂTOR AUTORIZAT

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Nr. **CE 669121**

Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Cu privire la:

A se vedea fila cu domeniul de aplicare al certificatului.

pe baza examinării noastre efectuate asupra sistemului de asigurare a calității, în temeiul cerințelor Directivei Consiliului 93/42/CEE, Anexa II cu excepția Secțiunii 4. Sistemul de asigurare a calității întrunește cerințele directivei. Pentru plasarea pe piață a produselor din Clasa III, este necesar un certificat conform Anexei II secțiunea 4.

Pentru și în numele BSI, Organism Notificat pentru Directiva de mai sus (Organism Notificat Numărul 0086):

Semnătură indescifrabilă
Stewart Brain, Director Conformitate & Risc-
Dispozitive Medicale

MINISTERUL JUSTIȚIEI
MUȘUROIA
MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Prima ediție: **20.07.2017** Data: **09.05.2018** Data expirării: **18.03.2023**

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Certificat nr. CE 669121

Domeniul de aplicare al Certificatului:

Proiectarea, dezvoltarea și fabricarea următoarelor produse:

Kit-uri de infuzie sterile, de unica folosinta, inclusiv casete, tuburi, conectori, ace

Unitati de incalzire pacient

Unitati de incalzire sange si fluide

Seturi sterile de unica folosinta incalzire sange si fluide

Sisteme sterile implantabile cu acces central

Sisteme sterile implantabile cu acces periferic

Acele aspecte din Anexa II cu privire la asigurarea și menținerea condițiilor sterile pentru paturici incalzire convectiva.

Prima ediție: **20.07.2017** Data: **09.05.2017** Data expirării: **18.03.2023**

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****

Subsemnata **MUSUROIA MIRELA,** traducator autorizat de Ministerul Justitiei, certific exactitatea acestei traducerii cu textul înscrisului original în limba engleza, ce a fost vizat de mine.

MINISTERUL JUSTIȚIEI MUȘUROIA MIRELA Aut. Nr. 2769 Engleză/Franceză TRADUCĂTOR AUTORIZAT

Traducător autorizat

Nr. 2769/2015

Valabilitatea acestui certificat este condiționată de menținerea sistemului calității în cerințele Directivei, demonstrate prin activitățile de supraveghere impuse de Organismul Notificat. Această aprobare exclude toate produsele create și/ sau fabricate de o parte terță în numele companiei numite în prezentul certificat, dacă nu se agreează în mod specific cu BSI.
Prezentul certificat a fost emis în formă electronică și este supus condițiilor contractului.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, înregistrată în Anglia sub numărul 7805321 la 389 Chiswick High Road, Londra W4 4AL, UK. Membră a Grupului de Companii BSI.

Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Subcontractor:	**Serviciu(ii) livrat(e)**
CarTika Medical Inc 6551 Wedgwood Rd N Suite 300 Maple Grove Minnesota 55311 SUA	**Producție**
Isomedix Operations Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 SUA	**Sterilizare ETO**
Isomedix Operations Inc. 7685 Saint Andrews Avenue San Diego California 92154 SUA	**Sterilizare ETO**

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

Lista principalilor subcontractori

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Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Isomedix Operations Inc. 43425 Business Park Drive Temecula California 92590 SUA	**Sterilizare ETO**
Isomedix Operations Inc. 23 Elizabeth Drive Chester New York 10918 SUA	**Sterilizare gamma**
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 55108 SUA	Proiectare Producție

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Recunoscuți ca fiind implicați în serviciile legate de produsul acoperit de:

Certificat Nr. **CE 669121**
Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Smiths Healthcare Manufacturing S.A de C.V. Avenida Calidad nr. 4 Parque Industrial Internacional Tijuana Baja California 22425 Mexic	**Producție**
Smiths Medical ASD, Inc. 1265 Grey Fox Road St Paul Minnesota 55112 SUA	**Respectarea reglementarilor**
Smiths Medical ASD, Inc. 3350 Granada Ave North Oakdale Minnesota 55128 SUA	**Producție**

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Smiths Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF Regatul Unit	**Reprezentanță UE**
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte Carolina de Nord 28278 SUA	**Sterilizare ETO**
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 SUA	**Sterilizare gamma**

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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Data: **09.05.2017**
Emis pentru: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
SUA

Subcontractor:	**Serviciu(ii) livrat(e)**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 SUA	**Sterilizare gamma**
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 SUA	**Sterilizare ETO**
Sterigenics US, LLC 84 Park Road Queensbury 12804 New York SUA	**Sterilizare ETO**

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Certificat CE – Sistem Complet de Asigurare a Calității

Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II cu excepția Secțiunii 4

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SUA

MINISTERUL JUSTIȚIEI
MUȘUROIA MIRELA
Aut. Nr. 2769
Engleză/Franceză
TRADUCĂTOR AUTORIZAT

Data	Număr referință	Acțiune
20 iulie 2017	8691798	Prima ediție, transferată de la un alt organism notificat
Curentă	8893340	Reinnoire, reformulare domeniu de aplicare, reducere domeniu de aplicare, eliminare subcontractori, corectie adrese subcontractori si activitati

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.

Informații și contact: BSI, Kitemark Court, Davy Avenue, Knowhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000

Certificate of Registration

This is to certify that the quality management system of

SMITHS MEDICAL CZECH REPUBLIC a.s.

Olomoucká 306, 753 01 Hranice, Czech Republic

has been assessed and registered by AMTAC Certification Services Limited as conforming to the requirements of:

EN ISO 13485:2012

The quality management system is applicable to:

The design, assembly, manufacture, packaging and supply of:

Obstetrics and Gynaecology Devices and Accessories,
Interventional Imaging Devices and Accessories,
Oxygen & Humidity Management Devices,
Pain Management Devices and Accessories,
Invasive Patient Pressure Monitoring Devices and Accessories,
Tracheostomy Devices,
Disposable Infusion Devices,
Suction Catheters Devices,
Intubation Systems Devices.

Certificate Number:	**1201-04 B**
Initial Certification Date:	**10 January 2014**
Certificate Effective Date:	**22 May 2017**
Certificate Expiry Date:	**28 February 2019**

UKAS MANAGEMENT SYSTEMS
061

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd