

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: **2020-11-09**

Expiry Date: **2023-03-18**

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Page 1 of 8

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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Page 2 of 8

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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.

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		
<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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Page 3 of 8

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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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Page 4 of 8

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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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Page 5 of 8

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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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Page 6 of 8

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NBOG code(s)	Device description	Intended purpose
Class IIa		
<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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Page 7 of 8

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NBOG code(s)	Device description	Intended purpose
Class IIa		
<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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Page 8 of 8

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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: **2020-11-09**
 Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
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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 United Kingdom	Manufacture
GaleMed (Xiamen) Co.,Ltd. Amoy Export Processing Zone 39 Section3, Haijing East Road Fujian Province 361026 China	Manufacture
GaleMed Corporation No. 87, Li-Gong 2nd Road Wu-Jia YILAN 268 Taiwan	Manufacture

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Subcontractor:	Service(s) supplied
GE Medical Systems Limited Pollards Wood Nightingales Lane Chalfont St Giles HP8 4SP United Kingdom	Manufacture
GKN Aerospace Service Limited T/A GKN Aerospace – Luton London Luton Airport Luton LU2 9PQ United Kingdom	Manufacture
GKN Aerospace Service Ltd - Cowes Site Falcon Road, East Cowes Isle of Wight, PO32 6RA United Kingdom	Manufacture

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Subcontractor:	Service(s) supplied
HA2 Medizintechnik GmbH Tchaikowskistrasse 2 38820 Halberstadt Germany	ETO Sterilization
Innovative Medical Manufacturing Company N°107 LN. 181 Sec. 1 Yongzhen Rd. Zhunan Township Miaoli County 35057 Taiwan (R.O.C)	Manufacture
Isomedix Operations, Inc. 380 90th Ave NW Minneapolis Minnesota 55433 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	ETO Sterilization
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	ETO Sterilization
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	ETO Sterilization

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USA

Subcontractor:	Service(s) supplied
Isomedix Operations, Inc. 23 Elizabeth Drive Chester New York 10918 USA	Gamma Irradiation
Kawasumi Laboratories (Thailand) Co., Ltd Nava Nakorn Promotion Zone 55/26 MU-13, Phahon Yothin Road KM-46, Tambon Khlong Nueng Amphoe Khlong Luang Changwat Phatum Thani 12120 Thailand	Manufacture
Koo Medical Equipment (Shanghai) Co., Ltd 100 Zhongde Road Dakun Industrial Park Songjiang, Shanghai 201614 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 USA	Manufacture
Medisize CZ s.r.o. Tovární 560 374 15 Trhové Sviny Czech Republic	Manufacture

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USA

Subcontractor:	Service(s) supplied
MicroMo Electronics Inc 14881 Evergreen Avenue Clearwater FL 33762 USA	Manufacture
Minnetronix, Inc. 1635 Energy Park Drive St Paul Minnesota 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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USA

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

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Minneapolis
Minnesota
55442
USA

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
 Massachusetts
 01420
 USA

Manufacture

Plexus Corp.
 2444 Schultz Drive
 Neenah
 Wisconsin 54957
 USA

Manufacture

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USA

Subcontractor:	Service(s) supplied
Poly Medisure Limited Unit II: Plot No. 115/116 Sector 59. HSIIDC Industrial Area Ballabhgarh Faridabad-121004 Haryana India	ETO Sterilization Manufacture
Providence Enterprise Limited No. 5-4 NeiHuan Road Shanxia Village, Pinghu Shenzhen 518111 China	Manufacture
Rolls Royce plc, Gypsy Patch Lane, Filton Bristol, BS34 7QE United Kingdom	Manufacture

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USA

Subcontractor:	Service(s) supplied
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
Smiths Healthcare Manufacturing SA de CV Carretera Miguel Aleman Km 21.7, Parque Industrial Monterrey, Apodaca NL CP 66603 Mexico	Manufacture

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USA

Subcontractor:	Service(s) supplied
Smiths Medical ASD Inc. 5700 West 23rd Avenue Gary Indiana 46406 USA	Manufacture
Smiths Medical ASD, Inc 10 Bowman Drive Keene New Hampshire 03431 USA	Manufacture
Smiths Medical ASD, Inc 6000 Nathan Lane North Minneapolis Minnesota 55442 USA	Design Manufacture

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Subcontractor:	Service(s) supplied
Smiths Medical ASD, Inc. 201 West Queen Street, Southington Connecticut 06489 United States	Manufacture Packaging
Smiths Medical ASD, Inc. 6250 Shier Rings Road Dublin Ohio 43016 United States	Manufacture
Smiths Medical ASD, Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	Manufacture

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Subcontractor:	Service(s) supplied
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
Smiths Medical International Limited Bramingham Business Park, Enterprise Way, Luton, Beds, LU3 4BU, United Kingdom	Manufacture

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Subcontractor:**Service(s) supplied**

Smiths Medical International Limited
1500 Eureka Park
Lower Pemberton
Ashford
Kent
TN25 4BF
United Kingdom

Manufacture

Smiths Medical International Ltd
52 Grayhill Rd
Westfield Industrial Estate
Cumbernauld
Glasgow
G68 9HQ
UK

Manufacture

Smiths Medical Italia S.r.l
Via della Stazione 2
Latina Scalo
Latina
04100
Italy

**Manufacture
Packaging**

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Subcontractor:

Service(s) supplied

Smiths Medical Nederland BV
 Smiths Medical
 International Bijsterhuizen 22 - 08
 6604 LD Wijchen,
 The Netherlands

Final Inspection

Smiths Medical North America
 9124 Polk Lane
 Olive Branch
 Mississippi
 38654
 USA

Final Inspection

Sovrin Plastics Ltd
 Stirling Road
 Slough
 Berkshire
 SL1 4ST
 United Kingdom

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Subcontractor:	Service(s) supplied
Sterigenics Belgium (Petit- Rechain) SA Zoning Industriel Avenue Andre Enst 21, Verviers Liège B-4800 Belgium	ETO Sterilization
Sterigenics Italy Spa via Marzabotto 4 Minerbio Bologna 40061 Italy	Radiation (Gamma Sterilization)
Sterigenics US, LLC 344 Bonnie Circle Corona California USA	Gamma Irradiation

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 1700 College Blvd West Memphis Arkansas 72301 USA	Gamma Irradiation
Sterigenics US, LLC 10811 Withers Cove Park Drive Charlotte North Carolina 28278 USA	ETO Sterilization
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	ETO Sterilization

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Subcontractor:	Service(s) supplied
Sterilisation Services of Georgia 6005 Boatrock Blvd Atlanta Georgia 30336 USA	ETO Sterilization
Sterilization Services of Tennessee 2396 Florida Street Memphis Tennessee 38109 USA	ETO Sterilization
Sterilization Services of Virginia 5674 Eastport Boulevard Richmond Virginia 23231 USA	ETO Sterilization

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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 669121**
Date: **2020-11-09**
Issued To: **Smiths Medical ASD Inc.**
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
STERIS S.p.A. Via Einaudi, 9 Calcinato (BG) 24050 Italy	ETO Sterilization
Synergy Health AST, Ede (Synergy Health PL, Ede) Morsestraat 3 Ede 6716 AH The Netherlands	Gamma Irradiation
Tae-Chang Industrial Co., Ltd (Gongju Plant) 8-18, Bojeokdong-gil Useong-myeon, Gongju-si, Chungcheongnam-do Korea	Manufacture

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Subcontractor:	Service(s) supplied
Teleflex Medical Wire Products, Inc. Teleflex Medical OEM Division 6550 Wedgewood Road North Suite 300 Maple Grove Minnesota 55311 USA	Manufacture
TOP Corporation 19-10 Senju Nakai-cho Adachi-ku, Tokyo 120-0035 Japan	Manufacture
Unisis Corp. 2675-1 Nishikata, Koshigaya-shi, Saitama, 343-0822 Japan	Manufacture

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Subcontractor:	Service(s) supplied
UPG Avenida La Cuspide #1 Parque Industrial Tecnomex Del. Playas de Tijuana Tijuana Baja California 22700 Mexico	Manufacture
Velcro USA Inc. 95 Sundial Avenue Manchester New Hampshire 03103-7206 USA	Crucial Supplier
Xeridiem Medical Devices 4700 South Overland Drive Tucson Arizona 85714-3430 USA	Manufacture Packaging

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Certificate History

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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

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Page 1 of 5

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

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Date	Reference Number	Action
		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 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

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Page 2 of 5

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Date	Reference Number	Action
		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, Noratron Suzhou Co., Ltd., Plexus Corp. , Providence Enterprises Limited, OSI Optoelectronics, Inc., Smiths Medical International Limited (Luton). Removal of: Sterigenics US, LLC (Willowbrook, Illinois), STERIS Applied Sterilization Technologie Formerly Synergy Health Applied Steriliz Addition of the supplementary device table.
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.

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Page 3 of 5

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Date	Reference Number	Action
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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Page 4 of 5

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Date	Reference Number	Action
Current	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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