

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F003328

Holds Certificate No:

MDSAP 705715

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 6

...making excellence a habit.™

Certificate No: **MDSAP 705715**

Registered Scope:

The design, development and manufacture of:

Sterile Disposable infusion kits including cassette, tubes, connectors, needles

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

Sterile Needles and Introducer for Implantable Access

Sterile Catheters and accessories

Sterile Blood Sampling Devices

Sterile Respiratory Therapy Devices and positive airway pressure therapy

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 Positive expiratory pressure therapy systems

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

-Non-Sterile filter

-And Sterile and Non-Sterile tracheostomy accessories

Sterile Disposable Pressure Monitoring tubes, connectors and transducers

Sterile Suction Catheters

Sterile Drainage Devices

Sterile Feeding devices

Sterile Cardiothoracic Catheters

Patient warming units; Blood and Fluid Warmers unit

Infusion Pumps for hospital and home use;

Infusion Application Software

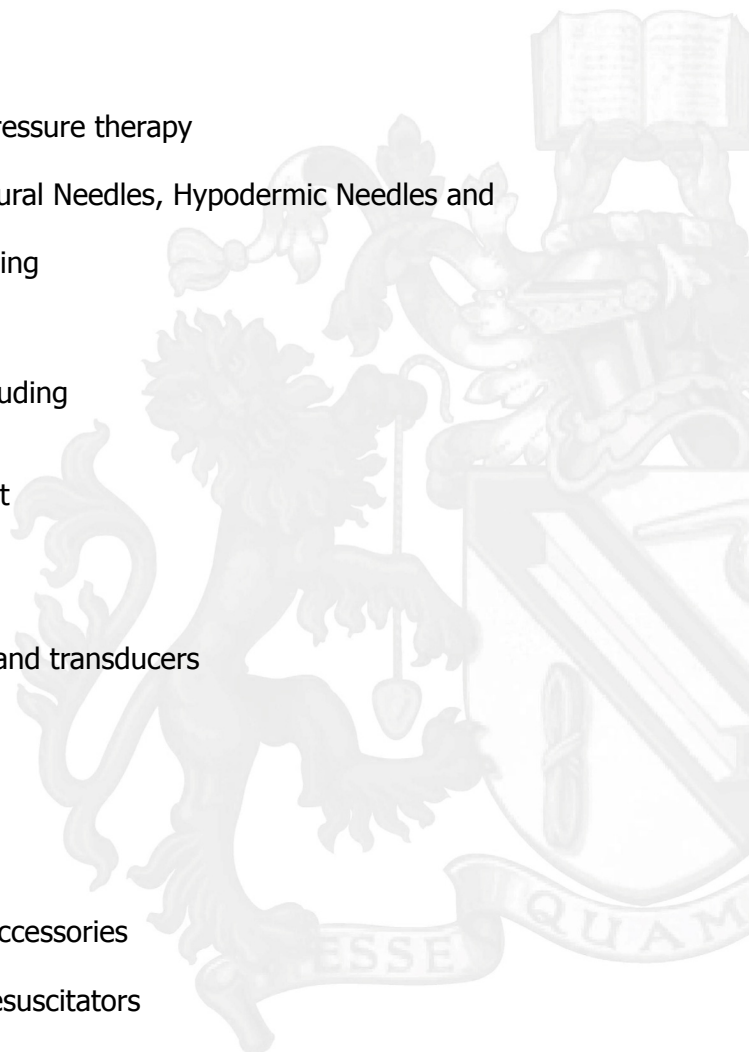
Sterile and non-sterile convective warmers blankets and accessories

Medical Gas Administration Accessories

Gas Powered Emergency and Transport Ventilators and Resuscitators

Anesthetic Ventilators, Monitors and Related Equipment

Non-Sterile Nebulizers



Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05

Page: 2 of 6

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.

Certificate No: **MDSAP 705715**

Registered Scope:

Sterile Regional Anesthesia Devices
Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia
Interventional Imaging Devices
Sterile Pain Management Devices
Sterile and Non-Sterile: Berman and Guedel Airways
Disposable Endotracheal Tubes
Heat and Moisture Exchanger for Anesthesia
Filter for Anesthesia; Disposable Anesthesia Masks
Vibratory Positive Expiratory Devices
Incentive Spirometers
Silicone Laryngeal Mask
Oxygen Line Accessory; Nasal Cannula
Oxygen Masks
Drainage Bags
Oxygen Tubing
Adult Face Tent
Disposable Anesthesia Face Masks
Sterile Guedel Airway
Sterile Berman Airway – Intubation Systems

The Servicing of Patient Warming units, Blood and Fluid Warmer units, Infusion Pumps for hospital and home use, Gas Powered Emergency and Transport Ventilators and Resuscitators, Anesthetic Ventilators and Monitors and Related Equipment



Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05

Page: 3 of 6

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 705715**

Location

Smiths Medical ASD Inc.
3350 Granada Avenue North
Oakdale
Minnesota
55128
USA
Facility ID Number: F003328

Registered Activities

The manufacture of:

Sterile Catheters and Accessories
Sterile and non sterile convective warmers blankets and accessories
Patient warming units
Sterile and non sterile vital sign monitoring probes
Blood and Fluid Warmers units
Sterile Blood and Fluid Warmers disposables sets
Infusion Application Software
Infusion Pumps for hospital and home use
Sterile Disposable infusion kits including cassette, tubes, connectors, needles
Medical Gas Administration Accessories
Servicing, distribution



Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05

Page: 4 of 6

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 705715**

Location

Smiths Medical ASD Inc.
6000 Nathan Lane North
Minneapolis
Minnesota
55442
USA
Facility ID Number: F003328

Registered Activities

The design, development and manufacturing of:

- Sterile Disposable infusion kits including cassette, tubes, connectors, needles
- 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
- Sterile Needles and Introducer for Implantable Access
- Sterile Catheters and accessories
- Sterile Blood Sampling Devices
- Sterile Respiratory Therapy Devices and positive airway pressure therapy
- 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 Positive expiratory pressure therapy systems
- 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
 - Non-Sterile filter
 - And Sterile and Non-Sterile tracheostomy accessories
- Sterile Disposable Pressure Monitoring tubes, connectors and transducers
- Sterile Suction Catheters
- Sterile Drainage Devices
- Sterile Feeding Devices
- Sterile Cardiothoracic Catheters
- Patient warming units
- Blood and Fluid Warmers units
- Infusion Pumps for hospital and home use
- Infusion Application Software
- Sterile and non sterile convective warmers blankets and accessories
- Medical Gas Administration Accessories
- Gas Powered Emergency and Transport Ventilators and Resuscitators
- Anesthetic Ventilators
- Monitors and Related Equipment
- Non-Sterile Nebulizers

Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05

Page: 5 of 6

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 705715**

Location

Registered Activities

Sterile Regional Anesthesia Devices
Sterile Needle safety devices and cough sampling devices and catheters securing devices and kit for applying local anesthesia
Interventional Imaging Devices
Sterile Pain Management Devices
Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.



Original Registration Date: 2020-04-06

Effective Date: 2021-09-14

Expiry Date: 2023-04-05

Page: 6 of 6

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.