

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

SMITHS HEALTHCARE MANUFACTURING S.A. DE C.V.

Main site: Avenida Calidad No 4, Parque Industrial Internacional Tijuana,
Tijuana, B.C. C.P. 22425 Mexico

has been registered by Intertek as conforming to the requirements of

EN ISO 13485:2016

The management system is applicable to:

Manufacture and inspection of anaesthesia breathing circuits,
anaesthesia breathing circuit accessories, tracheal products, epidural
catheters, suction catheters, temperature management products,
infusion drug delivery products, needle protection devices, infant
resuscitation devices and needle sets, airway accessories, tracheostomy
products and Implantable Port Access Systems.

*Previously certified by Intertek Certification AB to date 9 November 2020

Certificate Number:

0107359-01

Initial Certification Date:

2 February 2005*

Date of Certification Decision:

4 May 2021

Certificate Valid Date:

28 June 2021

Certificate Expiry Date:

27 June 2024



Ackred. nr. 10426
Certifiering av ledningssystem
ISO/IEC 17021-1



Intertek

Brian Mather

Certification Authority, Intertek Medical
Notified Body AB

Intertek Medical Notified Body AB
P.O. Box 1103, SE-164 22 Kista, Sweden



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 669191

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2017-08-16

Latest Revision Date: 2019-07-30

Effective Date: 2019-07-30

Expiry Date: 2022-04-19

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...making excellence a habit.™

Certificate No: **MD 669191**

Registered Scope:

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: 2017-08-16

Latest Revision Date: 2019-07-30

Effective Date: 2019-07-30

Expiry Date: 2022-04-19

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: **MD 669191**

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

Document Control, Post Market Risk Management, Customer Complaints, Global Sourcing, Regulatory Affairs, Servicing, distribution.

Previous certificates expires on 20/04/2019.

Recertification audit ended 22/03/2019.



Original Registration Date: 2017-08-16

Latest Revision Date: 2019-07-30

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 669191**

Location	Registered Activities
Smiths Medical ASD Inc. 3350 Granada Avenue North Oakdale Minnesota 55128 USA	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: 2017-08-16

Latest Revision Date: 2019-07-30

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Location

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6000 Nathan Lane North
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Sterile Blood Sampling Devices
Sterile Respiratory Therapy Devices and positive airway pressure therapy
Sterile Catheter Connectors<(>,<)>
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-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<(>,<)>
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Medical Gas Administration Accessories
Gas Powered Emergency and Transport Ventilators and Resuscitators
Anesthetic Ventilators
Monitors and Related Equipment
Non-Sterile Nebulizers

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Certificate No: **MD 669191**

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