

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Southmedic Inc.
50 Alliance Blvd
Barrie
Ontario
L4M 5K3
Canada

DUNS Number: 24-684-8147

Holds certificate No:

MDSAP 675962

Statement of Conformity: The company listed on this certificate has been audited to 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 [if design controls are part of the certification]; 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:



Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-04-30

Effective Date: 2018-06-19

Expiry date: 2021-04-26

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BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate No:

MDSAP 675962

Registered Scope:

Design, development, manufacture and distribution of open oxygen delivery devices, open oxygen delivery devices with carbon dioxide monitoring, oxygen masks with carbon dioxide monitoring, anaesthetic filling and closure systems, menstruation cups, sterile and non-sterile surgical blades, sterile and non-sterile disposable and safety scalpels, PVC and silicone tubing, connectors, nasal cannula, Kirschner surgical wires and Steinman surgical pins, and adult and pediatric face masks (aerosol and oxygen), blood collection kits, tracheostomy oxygen masks, sterile wound closures, and non-sterile vaginal pessary for the areas of respiratory therapy, anaesthesiology, gynaecology, general surgery and hemorrhoid banding systems.



Original Registration Date: 2018-04-30

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Expiry date: 2021-04-26

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This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: 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 675962

Location	Registered Activities
Southmedic Inc. 50 Alliance Blvd Barrie Ontario L4M 5K3 Canada DUNS Number: 24-684-8147	Design, development, manufacture and distribution of open oxygen delivery devices, open oxygen delivery devices with carbon dioxide monitoring, oxygen masks with carbon dioxide monitoring, anaesthetic filling and closure systems, menstruation cups, sterile and non-sterile surgical blades, sterile and non-sterile disposable and safety scalpels, PVC and silicone tubing, connectors, nasal cannula, Kirschener surgical wires and Steinman surgical pins, and adult and pediatric face masks (aerosol and oxygen), blood collection kits, tracheostomy oxygen masks, sterile wound closures, and non-sterile vaginal pessary for the areas of respiratory therapy, anaesthesiology, gynaecology, general surgery and hemorrhoid banding systems.
Southmedic Warehouse Units 14, 15 and 16 364 St. Vincent Street Barrie Ontario L4M 4A5 Canada DUNS Number: 24-684-8147	Distribution of open oxygen delivery devices, open oxygen delivery devices with carbon dioxide monitoring, oxygen masks with carbon dioxide monitoring, anaesthetic filling and closure systems, menstruation cups, sterile and non-sterile surgical blades, sterile and non-sterile disposable and safety scalpels, PVC and silicone tubing, connectors, nasal cannula, Kirschener surgical wires and Steinman surgical pins, and adult and pediatric face masks (aerosol and oxygen), blood collection kits, tracheostomy oxygen masks, sterile wound closures, and non-sterile vaginal pessary for the areas of respiratory therapy, anaesthesiology, gynaecology, general surgery and hemorrhoid banding systems.

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