

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

FM 643600

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following 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, 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 manufacture of hemorrhoid banding systems.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2015-11-19

Latest Revision Date: 2018-10-01

Effective Date: 2018-04-30

Expiry Date: 2021-04-26

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Certificate No: **FM 643600**

| Location | Registered Activities |
|---|--|
| Southmedic Inc. 50 Alliance Blvd Barrie Ontario L4M 5K3 Canada | 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 manufacture of hemorrhoid banding systems. |
| Southmedic Warehouse Units 14, 15 and 16 364 St. Vincent Street Barrie Ontario L4M 4A5 Canada | 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 closure devices and non-sterile vaginal pessary for the areas of respiratory therapy, anaesthesiology, gynaecology, general surgery and hemorrhoid banding systems. |

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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.