

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SunMed Holdings, LLC  
dba Ethox Medical LLC  
dba SunMed LLC  
dba Ventlab, LLC  
2710 Northridge Drive NW, Suite A  
Grand Rapids  
Michigan  
49544  
USA

Holds Certificate No:

**FM 701869**

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

The design, development, manufacture and distribution of anesthesia, respiratory, airway management, pressure infusion, wound irrigation, urology, operating room, and patient safety devices and accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-12-23

Latest Revision Date: 2020-04-27

Effective Date: 2020-04-27

Expiry Date: 2023-04-26

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Certificate No: **FM 701869**

Location	Registered Activities
Ethox Medical, LLC 2710 Northridge Drive NW, Suite A Grand Rapids Michigan 49544 USA	The design, development, manufacture and distribution of sterile and non-sterile instrument holders and accessories, blood pressure cuffs and accessories, tubing sets, wound irrigation devices, gastric lavage kits and pressure infusion devices. Provision for subcontract design, manufacture and packaging for medical devices and sterilization and laboratory services.
SunMed LLC 2710 Northridge Dr NW Suite A Grand Rapids Michigan 49544 USA	The design, development, manufacture and distribution of anesthesia, respiratory and urology accessories.
Ventlab, LLC 2710 Northridge Dr. NW Suite A Grand Rapids Michigan 49544 USA	<p>The design, development, manufacture and distribution of manual resuscitators, anesthesia mask, nasal CPAP interfaces, bacterial filters/HME products, nasal oxygen cannulae and face masks, nebulizers, humidifiers and CO2 indicators used in the areas of emergency respiratory and respiratory/anesthesia applications.</p> <p>The design, development, manufacture and distribution of surgical devices related to operating room accessories and patient safety.</p>

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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](http://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.