

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

DUNS Number: 07-971-4264

Holds Certificate No:

MDSAP 698604

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; 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, 21 CFR 821

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: 2020-04-27

Effective Date: 2020-04-27

Expiry Date: 2023-04-26



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 2

...making excellence a habit.™

Certificate No: **MDSAP 698604**

Location	Registered Activities
SunMed LLC 2710 Northridge Dr NW Suite A Grand Rapids Michigan 49544 USA DUNS Number: 07-971-4264	The design, development, manufacture and distribution of anesthesia, respiratory and urology accessories.
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.
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>

Original Registration Date: 2020-04-27

Effective Date: 2020-04-27

Expiry Date: 2023-04-26

Page: 2 of 2

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.