

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Aspen Surgical Products Inc.  
6945 Southbelt Drive, SE  
Caledonia  
Michigan  
49316  
USA

Facility ID Number: F000056

Holds Certificate No:

**MDSAP 690516**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-08-04

Effective Date: 2022-08-01

Expiry Date: 2024-05-20



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 690516**

## Registered Scope:

Design and Development, Manufacture and Distribution of General Surgical Devices. The scope of the registration includes the following products: Non-Sterile Procedure Masks, Surgical Masks, Isolation Gowns and Protective Gowns and Sterile and Non-Sterile Surgical Blades and Scalpels, Scalpel handles, Scalpel Covers, Kittners, Snares, Vessel Loops, Surgical Needles, Bulb Evacuators and Collection System, Wound Drains, Clamp Covers, Suture Boots, Endoscopic Fog Inhibitor, Surgical Light Handle and Camera Covers, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Pin Covers, Patient Positioning, Suture Retrievers, Ultrasound Needle Guides, Protective Covers and Imaging Accessories, and Obstetric and Pediatric devices including Amnihook Membrane Perforators, Umbilical Cord Clamps, Circumcision Devices and U-Bags.



Original Registration Date: 2021-08-04

Effective Date: 2022-08-01

Expiry Date: 2024-05-20

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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.

Certificate No: **MDSAP 690516**

Location	Registered Activities
Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA Facility ID Number: F000056	Design and Development, Manufacture and Distribution of General Surgical Devices. The scope of the registration includes the following products: Non-Sterile Procedure Masks, Surgical Masks, Isolation Gowns and Protective Gowns and Sterile and Non-Sterile Surgical Blades and Scalpels, Scalpel handles, Scalpel Covers, Kittners, Snares, Vessel Loops, Surgical Needles, Bulb Evacuators and Collection System, Wound Drains, Clamp Covers, Suture Boots, Endoscopic Fog Inhibitor, Surgical Light Handle and Camera Covers, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Pin Covers, Patient Positioning, Suture Retrievers, Ultrasound Needle Guides, Protective Covers and Imaging Accessories, and Obstetric and Pediatric devices including Amnihook Membrane Perforators, Umbilical Cord Clamps, Circumcision Devices and U-Bags.
Aspen Surgical Products Inc. 6885 Southbelt Drive, SE Caledonia Michigan 49316 USA Facility ID Number: F000056	Manufacturing and Distribution.
Aspen Surgical Products Inc. 5145 Beltway Drive SE Caledonia Michigan 49316 USA Facility ID Number: F000056	Distribution.

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