

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

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

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-08-04

Effective Date: 2021-08-04

Expiry Date: 2024-05-20



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 2

...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: Sterile and Non-Sterile Surgical Blades and Scalpels, Scalpel handles, Scalpel Covers, Kittners, Snares, Vessel Loops, Surgical Needles, Bulb Evacuator and Collection System, Silicone Vessel Loops, 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.



Original Registration Date: 2021-08-04 Effective Date: 2021-08-04

Expiry Date: 2024-05-20

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](#). 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.