

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

Holds Certificate No:

FM 703043

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following 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 Accessories, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Pin Covers, Alginate, Chitosan, Film and Silver Wound Care Dressings, Ophthalmic Cannula, Specialty Needles and Probes.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2010-12-09

Latest Revision Date: 2018-10-30

Effective Date: 2018-05-21

Expiry Date: 2021-05-20

Page: 1 of 2



...making excellence a habit.™

Certificate No: **FM 703043**

Location	Registered Activities
Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA	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 Accessories, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Pin Covers, Alginate, Chitosan, Film and Silver Wound Care Dressings, Ophthalmic Cannula, Specialty Needles and Probes.
Aspen Surgical Products Inc. 6885 Southbelt Drive, SE Caledonia Michigan 49316 USA	Manufacturing and Distribution.
Aspen Surgical Products Inc. 5220 68th Street Caledonia Michigan 49316 USA	Distribution

Original Registration Date: 2010-12-09

Effective Date: 2018-05-21

Latest Revision Date: 2018-10-30

Expiry Date: 2021-05-20

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](http://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.