

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: 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2010-12-09

Latest Revision Date: 2022-03-25

Effective Date: 2021-05-21

Expiry Date: 2024-05-20



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: 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	Manufacturing and Distribution.
Aspen Surgical Products Inc. 5145 Beltway Drive SE Caledonia Michigan 49316 USA	Distribution

Original Registration Date: 2010-12-09

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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](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.

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A Member of the BSI Group of Companies.