

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 Number:

FM 703043

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2010-12-09

Latest Revision Date: 2023-12-12

Effective Date: 2021-05-21

Expiry Date: 2024-05-20

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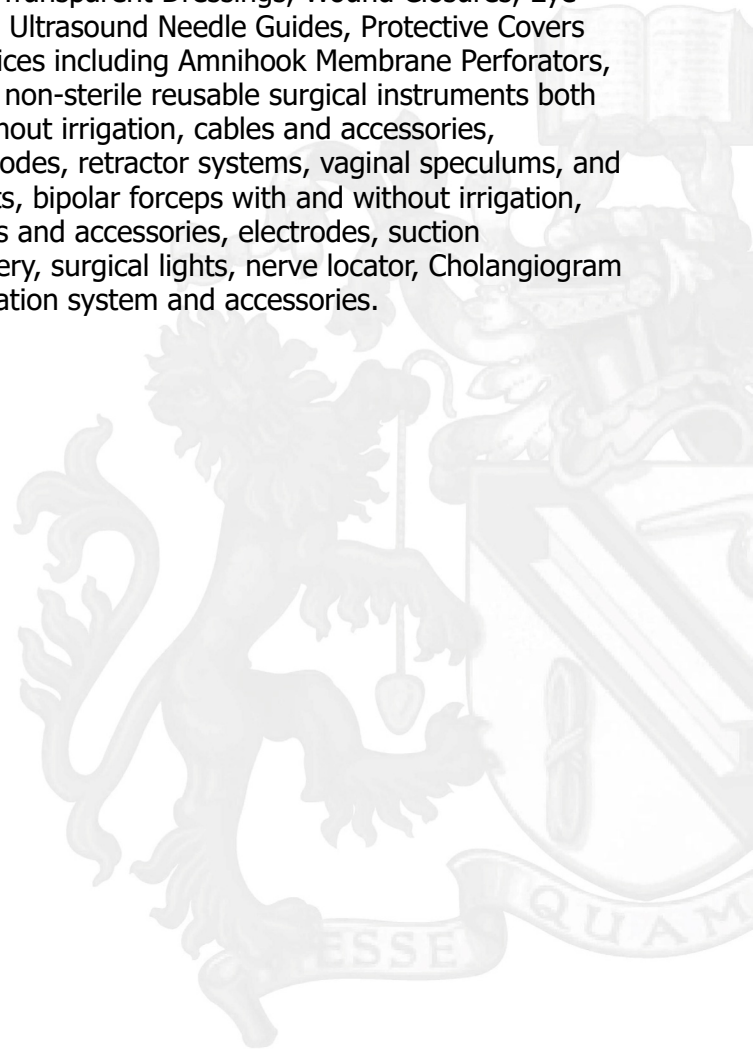


...making excellence a habit.™

Certificate No: FM 703043

Registered Scope:

Design and develop, manufacture, service, and distribution of, General Surgical Devices, electrosurgical, manual surgical, and neurosurgical instruments and accessories. 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, Sponges, Dissectors, Kittners, Snares, Vessel Loops, Surgical Needles, Bulb Evacuators and Collection System, Wound Drains, Towel Clamps, Clamp Covers, Suture Boots, Endoscopic Fog Inhibitor, Surgical Light Handle and Camera Covers, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Eye Bubble, 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, non-sterile reusable surgical instruments both handheld and non-handheld, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, retractor systems, vaginal speculums, and sterilization containers; Sterile disposable surgical products, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, suction coagulators, and retractor systems. ESU Generators, cautery, surgical lights, nerve locator, Cholangiogram catheter, Ophthalmic burrs and handle, and Smoke evacuation system and accessories.



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Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

Certificate No: FM 703043

Location	Registered Activities
Aspen Surgical Products Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA	Design and develop, manufacture, service, and distribution of, General Surgical Devices, electrosurgical, manual surgical, and neurosurgical instruments and accessories. 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, Sponges, Dissectors, Kittners, Snares, Vessel Loops, Surgical Needles, Bulb Evacuators and Collection System, Wound Drains, Towel Clamps, Clamp Covers, Suture Boots, Endoscopic Fog Inhibitor, Surgical Light Handle and Camera Covers, Marking Pens, Cautery Tip Cleaners, Transparent Dressings, Wound Closures, Eye Bubble, 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, non-sterile reusable surgical instruments both handheld and non-handheld, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, retractor systems, vaginal speculums, and sterilization containers; Sterile disposable surgical products, bipolar forceps with and without irrigation, cables and accessories, monopolar forceps, pencils, cables and accessories, electrodes, suction coagulators, and retractor systems. ESU Generators, cautery, surgical lights, nerve locator, Cholangiogram catheter, Ophthalmic burrs and handle, and Smoke evacuation system and accessories.
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

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