

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

United States Endoscopy Group, Inc.
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

Facility ID Number: F000463

Holds Certificate No:

MDSAP 687491

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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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 Global Regulatory & Quality

Original Registration Date: 2019-08-21

Effective Date: 2024-12-22

Expiry Date: 2027-12-21



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 687491**

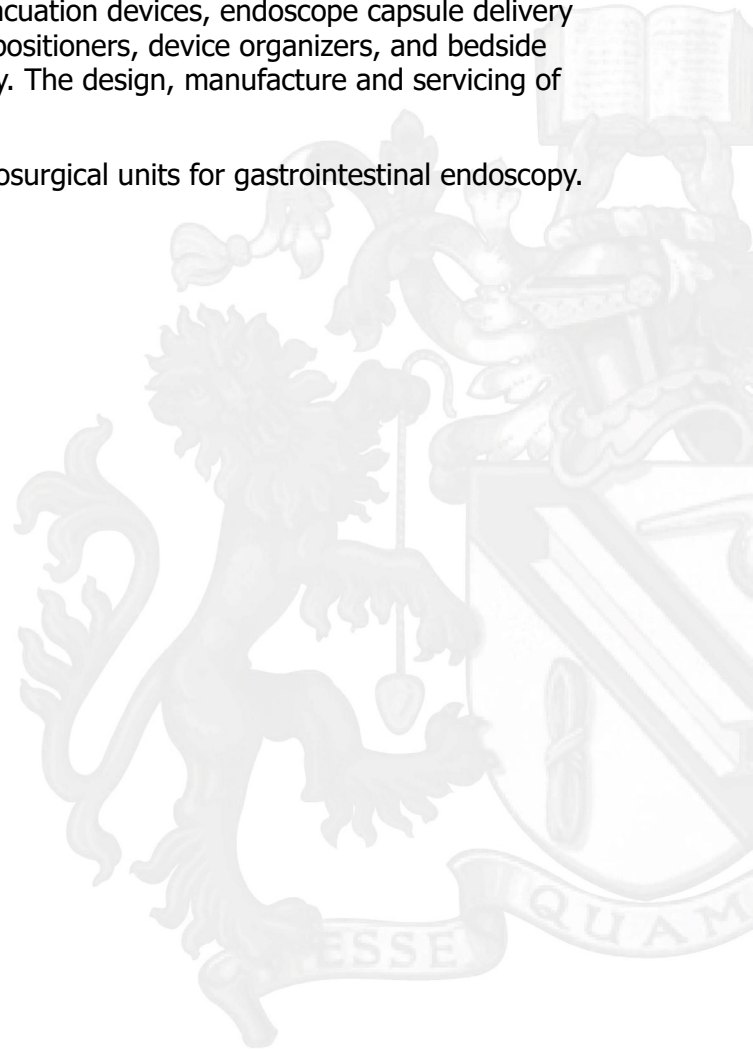
Registered Scope:

The design and manufacture of sterile biopsy forceps, injection needles, clips, tissue sampling devices, grasping devices, endoscope valves, endoscope attachment caps, electro-surgical and non-electro-surgical snares, cryosurgical catheters, and cryosurgical suction tubes for gastrointestinal endoscopy.

The design and manufacture of sterile and non-sterile retrieval devices, EUS balloons, biopsy valves and endoscope tip protectors for gastrointestinal endoscopy.

The design and manufacture of non-sterile overtubes, evacuation devices, endoscope capsule delivery devices, bite blocks, polyp traps, cleaning brushes, head positioners, device organizers, and bedside endoscope cleaning devices for gastrointestinal endoscopy. The design, manufacture and servicing of powered insufflators for gastrointestinal endoscopy.

The design, manufacture, servicing and installation of cryosurgical units for gastrointestinal endoscopy.



Original Registration Date: 2019-08-21

Effective Date: 2024-12-22

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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](#). 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.

Certificate No: **MDSAP 687491**

Location

Registered Activities

United States Endoscopy Group, Inc.
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA
Facility ID Number: F000463

The design of sterile biopsy forceps, injection needles, clips, tissue sampling devices, grasping devices, endoscope valves, endoscope attachment caps, electrosurgical and non-electrosurgical snares, cryosurgical catheters and cryosurgical suction tubes. The design of sterile and non-sterile retrieval devices, EUS balloons, biopsy valves and endoscope tip protectors.
The design of non-sterile overtubes, evacuation devices, endoscope capsule delivery devices, bite blocks, polyp traps, cleaning brushes, head positioners, device organizers, bedside endoscope cleaning devices, powered insufflators and cryosurgical units. The manufacture of sterile biopsy forceps, clips, tissue sampling devices, and grasping devices. The manufacture of sterile and non-sterile EUS balloons. The manufacture of non-sterile evacuation devices, endoscope capsule delivery device, endoscope tip protectors, bite blocks, cleaning brushes, head positioners, device organizers, bedside endoscope cleaning devices, and polyp traps.
The manufacture and servicing of powered insufflators. The manufacture, servicing and installation of cryosurgical units for gastrointestinal endoscopy.

United States Endoscopy Group, Inc.
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The manufacture of sterile injection needles, tissue sampling devices, grasping devices, endoscope valves, electrosurgical and non-electrosurgical snares, and endoscope attachment caps.
The manufacture of sterile and non-sterile retrieval devices, biopsy valves, and endoscope tip protectors.
The manufacture of non-sterile overtubes, and cleaning brushes.

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