

# 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**

Statement of Conformity: The company listed on this certificate has been audited 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: 2019-08-21

Effective Date: 2021-12-22

Expiry Date: 2022-12-21



BSI Group America Inc. is an MDSAP authorized auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 687491**

## Registered Scope:

Design and Manufacture of sterile and non-sterile, active and non-active devices for Endoscopy including the following: Snares, Biopsy Forceps, Retrieval Devices, Injection Needles, Tissue Sampling Devices, Procedure Packs, Biopsy Valves, Disposable Overtubes, Irrigation Devices, Hemostasis Devices, Evacuation Devices and Endoscopic Accessories. Design, manufacture and distribution of powered insufflators and related sterile and non-sterile administration sets and servicing of powered insufflators.

Design, manufacture and servicing of cryosurgical units and related accessories.



Original Registration Date: 2019-08-21

Effective Date: 2021-12-22

Expiry Date: 2022-12-21

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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](http://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

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

United States Endoscopy Group, Inc.  
6091 Heisley Road  
Mentor  
Ohio  
44060  
USA  
Facility ID Number: F000463

Registered Activities

Design, Manufacture and servicing of sterile and non-sterile, active and non-active devices for Endoscopy including the following: Snares, Biopsy Forceps, Retrieval Devices, Injection Needles, Tissue Sampling Devices, Procedure Packs, Biopsy Valves, Disposable Overtubes, Irrigation Devices, Hemostasis Devices, Evacuation Devices and Endoscopic Accessories.  
Design and manufacture of powered insufflators and related sterile and non-sterile administration sets and servicing of powered insufflators.

Design, manufacturer and service of cryosurgical units, catheters, and suction tubing.

Manufacture, Inspection and Storage of sterile and non-sterile, active and non-active devices for Endoscopy including the following: Snares, Biopsy Forceps, Retrieval Devices, Injection Needles, Tissue Sampling Devices, Procedure Packs, Biopsy Valves, Disposable Overtubes, Irrigation Devices, Hemostasis Devices, Evacuation Devices and Endoscopic Accessories.

Design, manufacture and service of cryosurgical units, catheters and suction tubing.

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