

# 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

Holds Certificate No:

**FM 75888**

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

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-04-18

Latest Revision Date: 2021-10-07

Effective Date: 2021-12-22

Expiry Date: 2022-06-21

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...making excellence a habit.™

Certificate No: **FM 75888**

Location

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

United States Endoscopy Group, Inc.  
6091 Heisley Road  
Mentor  
Ohio  
44060  
USA

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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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](https://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.