

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, Manufacture and Distribution 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, Cholangiocatheters, 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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-04-18

Latest Revision Date: 2019-08-21

Effective Date: 2019-01-01

Expiry Date: 2021-12-21

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Certificate No: **FM 75888**

Location	Registered Activities
United States Endoscopy Group, Inc. Also trading as US Endoscopy 5976 Heisley Road Mentor Ohio 44060 USA	Design, Manufacture and Distribution 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, Cholangiocatheters, 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.
United States Endoscopy Group, Inc. 6091 Heisley Road Mentor Ohio 44060 USA	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, Cholangiocatheters, Biopsy Valves, Disposable Overtubes, Irrigation Devices, Hemostasis Devices, Evacuation Devices and Endoscopic Accessories.



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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.

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A Member of the BSI Group of Companies.