By Royal Charter

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: 2025-07-08 Expiry Date: 2027-12-21

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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, electrosurgical and non-electrosurgical 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: 2025-07-08 Expiry Date: 2027-12-21

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. 6091 Heisley Road Mentor Ohio 44060 USA Facility ID Number: F000463	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.
STERIS Corporation 5960 Heisley Road Mentor Ohio 44060 USA Facility ID Number: F000422	Internal audits, vigilance reporting, recall, and marketing authorization activities.

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