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**

Statement of Conformity: The company listed on this certificate has been audited to 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: 2024-12-21

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

...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: 2024-12-21

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

Original Registration Date: 2019-08-21 Effective Date: 2021-12-22 Expiry Date: 2024-12-21