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 Number: 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2003-04-18
Effective Date: 2021-12-22
Latest Revision Date: 2022-09-15
Expiry Date: 2024-12-21

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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 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	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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