bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 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:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2003-04-18 Effective Date: 2018-01-31 Expiry Date: 2018-12-31

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

...making excellence a habit.™

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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