EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 770223 R000

Manufacturer: United States Endoscopy Group, Inc.

Address:
5976 Heisley Road
Mentor
Ohio
44060
USA

Single Registration Number: US-MF-000017968

EU Authorised Representative: STERIS Ireland Limited

Address:
IDA Business & Technology Park
Tullamore
Co. Offaly
R35 X865
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-07-21**

Current Issue Date: **2025-02-19**

Starting Validity Date: **2025-02-19**

Expiry Date: **2028-07-20**

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Device Schedule: Class III and Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Endoscopy Haemostasis Clips	The device is intended for use in flexible endoscopy and for the compression of tissue in the gastrointestinal tract, for hemostasis or for treating lesions of the wall of the gastrointestinal organs.
Class IIb	**Intended purpose**
Electrosurgery Snares/Electrodes	The device is an electrosurgical device designed to be used to endoscopically grasp, dissect, and transect tissue during Gastrointestinal (GI) endoscopic procedures. The snare can be used with or without the use of monopolar diathermic energy.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Endoscopic Injection needles	Class IIa
Non-Active Non-Implantable Gastrointestinal Endoscopy Instruments	Class IIa
Gastrointestinal Endoscopy Devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-07-21	3674952	Issued
2023-12-11	30054665	Supplemented – Addition of device category, MDN1208 - Non-active non-implantable gastrointestinal endoscopy instruments. Amended - Removed "Also trading as US Endoscopy" from manufacturer name.
Current	30340528	Supplemented – Addition of device category Endoscopic Injection needles, device group Endoscopy Haemostasis Clips and Electrosurgery Snares/Electrodes. Amended – Removed "MDN1208" and "G03" from the device schedule.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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