By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01922**

Issued To: **United States Endoscopy Group, Inc.**
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

In respect of:

The design and manufacture of the following sterile and non-sterile endoscopic devices, electrosurgical snares, biopsy forceps and haemostasis probes, injection needles, retrieval devices, tissue sampling devices, haemostasis clips, irrigation devices, powered insufflator systems and related sterile and non-sterile administration sets and endoscopic accessories. Those aspects of Annex II related to securing and maintaining sterility in the assembly of endoscopic procedure packs, in accordance with Article 12 of the Directive. The design and manufacture of cryosurgical units and related sterile accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-05-15** Date: **2021-05-14** Expiry Date: **2023-05-14**

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Supplementary Information to CE 01922

Issued To:

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Device Code(s)	Device Name	Intended purpose per IFU
Class IIb		
MD 1104	Electrosurgical Snares	Electrodes (ELEC) Polypectomy, tissue acquisition & Bleed Management
MD 1104	Biopsy Forceps	
MD 1104	Haemostasis Probe	
MD 0106	Haemostasis clips	Haemostasis clips
MD 1104 MDS 7010	TruFreeze System and accessories	Cryosurgical device and Cryosurgical accessories.
MD 0102	Injection Needles	Endoscopic Injection needles
Class IIa		
MD 0102	Irrigation devices	---
MD 0106	Tissue sampling device	---
MD 0106	Endoscopic accessories	---
MD 1104 MDS 7010	Endoscopic Insufflator	---
MD 0102	Endoscopic Insufflator accessories	---

First Issued: **1998-05-15** Date: **2021-05-14** Expiry Date: **2023-05-14**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 01922**
Date:	**2021-05-14**
Issued To:	**United States Endoscopy Group, Inc.** **Also trading as US Endoscopy** **5976 Heisley Road** **Mentor** **Ohio** **44060** **USA**

Subcontractor:	**Service(s) supplied**
Forefront Medical Investment (Pte) LTD 35 Joo Koon Circle Singapore 629110 Singapore	**Manufacture**
Isomedix Operations, Inc 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	**ETO Sterilization**
Isomedix Operations, Inc. 2072 Southport Road Spartanburg South Carolina 29306 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan UT 84095 USA	**Design** **Manufacture** **Regulatory Compliance**
Norman Noble, Inc. 5507 Avion Park Drive Highland Heights Ohio 44143 USA	**Manufacture**
Northgate Technologies Inc. (Nortech) 1591 Scottsdale Court Elgin Illinois 60123 USA	**Control of Sterilization** **Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Robling Medical, Inc. 90 Weathers Street Youngsville North Carolina NC 27596 USA	**Control of Sterilization** **Manufacture**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Radiation (Gamma Sterilization)**
STERIS Ireland Limited IDA Business & Technology Park Tullamore Co. Offaly R35 X865 Ireland	**EU Representative**

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List of Significant Subcontractors

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Subcontractor:	**Service(s) supplied**
United States Endoscopy Group, Inc. 6091 Heisley Road Mentor Ohio 44060 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01922**

Date: **2021-05-14**

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Date	Reference Number	Action
15 May 1998		First issue
24 July 2003		First renewal in new format
31 August 2007	7008481	Reissue due to extension to scope to include electrosurgical devices. The addition of Biosearch Medical Products, Inc. as a significant subcontractor for manufacture and the removal of Ethox Corp for microbiology service
03 April 2008	7185527	Certificate renewal Change of sub-contractor name from `Medical Manufacturing Corporation' to `Ethox International, MMC Sterilization Services Group'

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01922**

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Date	Reference Number	Action
24 February 2011	7635468	The addition of Steris Isomedix Services as a significant subcontractor for sterilization. The addition of Diagmed as EU Representative. The replacement of significant subcontractor Biosearch Medical Products Inc. by Merit Medical. Change of company name from 'United States Endoscopy Group, Inc. to 'United States Endoscopy Group, Inc., Also trading as US Endoscopy, Also trading as US Urology'.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
30 April 2013	7957820	Certificate renewal. History page correction - missing 2008 entry (7185527) returned. Irrigation devices added to scope. Scope clarified with more explicit device descriptions. Addition of US Endoscopy, Inc., 6091 Heisley Road to List of Significant Subcontractors for manufacture. Correction of activities for subcontractor Merit - design and regulatory compliance added. Removal of 'US Urology' trading name.
28 November 2014	8251964	Certificate reissue due to clarification of scope to more specifically reference endoscopic accessories.

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Date	Reference Number	Action
25 September 2015	8373259	Certificate reissue due to the addition of Forefront Medical Technology (Jiangsu) Co., Ltd. as a significant subcontractor for manufacture. Change of name of significant subcontractor Ethox International, MMC Sterilization Services Group to iuvo BioScience - Erie, LLC.
18 March 2016	8488331	Certificate reissue due to the addition to scope of powered insufflator systems and related sterile and non-sterile administration sets. Addition of Northgate Technologies Inc. (Nortech) as a significant subcontractor for design, manufacture and control of sterilization, and Sterigenics US, LLC, Gurnee, Illinois for gamma sterilization.
10 April 2017	8689356	Certificate reissue to add article 12 procedure packs to the scope.

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Date	Reference Number	Action
05 October 2017	8779098	Certificate re-issue – Extension to scope to add Haemostasis Clips. Addition of sub-contractors – Aponos medical corporation for manufacture.
30 April 2018	8935967	Certificate renewal. Remove sub-contractor iuvo BioScience. Remove PEG Procedure packs and Cholongiocatheters from certificate scope.
22 February 2019	9674784	Addition of Isomedix Operations, Inc., Spartanburg as ETO sterilization sub-contractor. Change of EU Authorized Representative to STERIS Ireland Ltd.
22 February 2019	7781677	Traceable to NB 0086.

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Date	Reference Number	Action
Current	3389235	Added "The design and manufacture of cryosurgical units and related sterile accessories" to scope statement. Added Device table. Removed subcontractors "Forefront Medical Ltd" and "Aponos Medical Corp.". Added subcontractors "Forefront Medical Investment (Pte) LTD", "Norman Noble, Inc." and "Robling Medical, Inc.".