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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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01922

Issued To:

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

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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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**
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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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**
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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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**
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**

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

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'

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EC Certificate - Full Quality Assurance System Certificate History

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

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'.

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EC Certificate - Full Quality Assurance System Certificate History

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

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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EC Certificate - Full Quality Assurance System Certificate History

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

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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EC Certificate - Full Quality Assurance System Certificate History

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

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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EC Certificate - Full Quality Assurance System Certificate History

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

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.".

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

10 Aug 2023

Notified Body Confirmation Letter

Reference: EU2023-607/670516

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number: US-MF-000017968

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written

agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Alan Till

Digitally signed by Alan Till
Date: 2023.08.10 15:04:21 +01'00'

Alan Till

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HISTOLOCK RESECTION DEVICE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
COINTIP SNARE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
LARIAT SNARE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
ISNARE SYSTEM-LARIAT SNARE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
ARTICULATOR-INJECTION NEEDLE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
CARR-LOCKE-INJECTION NEEDLE	Class IIb - Non Implantable	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
MORAY MICRO FORCEPS	Class IIa	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
PADLOCK CLIP DEFECT CLOSURE DEVICE **PADLOCK CLIP PRO-SELECT DEFECT CLOSURE DEVICE**	Class IIb - Implantable - WET	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797
HISTOGUIDE WIRE GUIDED FORCEPS	Class IIa	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
EXACTO COLD SNARE	Class IIa	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
ROTH NET Platinum	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ROTH NET FOREIGN BODY – STANDARD, MAXI, MINI	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
ROTH NET RETRIEVER - SELECT	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
ROTH NET RETRIEVER - 360	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
TALON GRASPING DEVICE	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
RAPTOR GRASPING DEVICE **RAPTOR GRASPING DEVICE - MINI**	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
BIOSHIELD BIOPSY VALVE-STERILE	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
BIOSHIELD BIOPSY VALVE EUS-LINEAR, STERILE	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
PROARMOR ENDOSCOPE TIP PROTECTOR	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
INFINITY ERCP SAMPLING DEVICE	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
INFINITY CYTOLOGY BRUSH	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
ORACLE EUS LATEX BALLOON, OLYMPUS RADIAL **ORACLE EUS LATEX BALLOON, OLYMPUS LINEAR**	Class Is	Not Applicable	EC Certificate # 02112 Expiry date May 14, 2023 NB# 2797
REVEAL DISTAL ATTACHMENT CAP	Class Is	Not Applicable	EC Certificate # 01922 Expiry date May 14, 2023 NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/08/10	Initial issue

Manufacturer's Declaration

In relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	United States Endoscopy Group, Inc. Also trading as US Endoscopy
Manufacturer address and contact details	5976 Heisley Road Mentor, OH 44060 US Coletta Cohara Director Quality & Regulatory Compliance Coletta_Cohara@STERIS.com
Single Registration Number (SRN) (if available)	US-MF-000017969

Authorised Representative name (if applicable)	STERIS Ireland Limited
Authorised Representative address and contact details	IDA Business and Technology Park Tullamore, County Offaly R35 X865 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000010065

Notified body name (if applicable)	BSI □ See attached schedule
Notified body number (if applicable)	2797 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE01922 CE02112 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-05-14 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Manufacturer's Declaration

End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

---

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Declaration

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

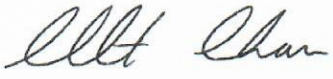
➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: United States Endoscopy Group, Inc., also trading as US Endoscopy

Location & Date: 5976 Heisley Road, Mentor, Ohio 44060 US, September 11, 2023

Signature: 

Print Name: Coletta Cohara

Title: Director Quality & Regulatory Compliance

Manufacturer's Declaration

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
HISTOLOCK RESECTION DEVICE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
COINTIP SNARE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
LARIAT SNARE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
ISNARE SYSTEM-LARIAT SNARE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
ARTICULATOR-INJECTION NEEDLE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
CARR-LOCKE-INJECTION NEEDLE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
PADLOCK CLIP DEFECT CLOSURE DEVICE	CE 01922	2023-05-14	BSI, 2797	2027-12-31	N/A
PADLOCK CLIP PRO-SELECT DEFECT CLOSURE DEVICE	CE 01922	2023-05-14	BSI, 2797	2027-12-31	N/A
MORAY MICRO FORCEPS	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
HISTOGUIDE WIRE GUIDED FORCEPS	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
EXACTO COLD SNARE	CE 01922	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET FOREIGN BODY-STANDARD	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET FOREIGN BODY-MAXI	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET FOREIGN BODY-MINI	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET PLATINUM-UNIVERSAL	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET PLATINUM-POLYP	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET-SELECT	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ROTH NET-360	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
TALON GRASPING DEVICE	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
RAPTOR GRASPING DEVICE	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
RAPTOR GRASPING DEVICE - MINI	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
BIOSHIELD BIOPSY VALVE-STERILE	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
BIOSHIELD BIOPSY VALVE EUS-LINEAR, STERILE	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
PROARMOR ENDOSCOPE TIP PROTECTOR	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
INFINITY ERCP SAMPLING DEVICE	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ORACLE EUS LATEX BALLOON, OLYMPUS RADIAL	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
ORACLE EUS LATEX BALLOON, OLYMPUS LINEAR	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A
REVEAL DISTAL ATTACHMENT CAP	CE 02112	2023-05-14	BSI, 2797	2028-12-31	N/A