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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 02112**

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

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of class I sterile devices for endoscopy.

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

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

Albert Roossien, Regulatory Lead

First Issued: **1998-09-29** Date: **2019-02-22** Expiry Date: **2023-05-14**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 02112**
Date:	**2019-02-22**
Issued To:	**United States Endoscopy Group, Inc.** **Also trading as US Endoscopy** **5976 Heisley Road** **Mentor** **Ohio** **44060** **USA**

Subcontractor:	**Service(s) supplied**
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**
STERIS Ireland Limited IDA Business & Technology Park Tullamore Co. Offaly R35 X865 Ireland	**EU Representative**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 02112**
Date:	**2019-02-22**
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 - Production Quality Assurance Certificate History

Certificate No: **CE 02112**

Date: **2019-02-22**

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

Date	Reference Number	Action
29 September 1998		First issue
24 July 2003		First renewal in new format
03 April 2008	7185527	Certificate renewal Change of sub-contractor name from "Medical manufacturing Corporation" to Ethox International, MMC Sterlization Services Group" Removal of "Ethox Corp" for microbiology service
24 February 2011	7635467	The addition of Steris Isomedix Services as a significant subcontractor for sterilization. The addition of Diagmed as EU Representative. 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'.
30 April 2013	7957821	Certificate renewal. Correction to History page entry 7185527 – '....Services Division' changed to '....Services Group' Addition of US Endoscopy, Inc., 6091 Heisley Rosd to list of significant subcontractors for manufacture. Removal of 'US Urology' trading name.

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By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 02112**

Date: **2019-02-22**

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	8405902	Change of name of significant subcontractor Ethox International, MMC Sterilization Services Group to iuvo BioScience - Erie, LLC.
04 May 2018	8900019	Certificate Renewal. Remove of significant subcontractor iuvo BioScience – Erie, LLC. Change name of significant subcontractor STERIS Isomedix Services, Inc. to Isomedix Operations, Inc.
22 February 2019	9674798	Addition of Isomedix Operations, Inc., Spartanburg as ETO sterilization sub-contractor. Change of EU Authorized Representative to STERIS Ireland Ltd.
Current	7781677	Traceable to NB 0086.

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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, 2023-06-14

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