

EC Certificate - Production Quality Assurance

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

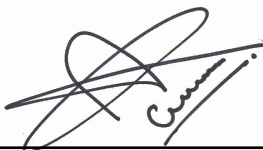
No. CE 02112
Issued To: **United States Endoscopy Group, Inc.**
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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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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**
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5976 Heisley Road
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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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Subcontractor:

Service(s) supplied

United States Endoscopy Group, Inc.
6091 Heisley Road
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Manufacture

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EC Certificate - Production Quality Assurance Certificate History

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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 Sterilization 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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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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