

EC Certificate - Full Quality Assurance System

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

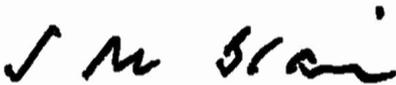
No. CE 01922
Issued To: **United States Endoscopy Group, Inc.**
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

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.

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-05-15**

Date: **2018-04-30**

Expiry Date: **2023-05-14**

...making excellence a habit.™

Page 1 of 1

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.

EC Certificate - Production Quality Assurance

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

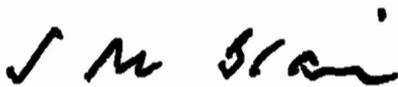
No. CE 02112
Issued To: **United States Endoscopy Group, Inc.**
Also trading as US Endoscopy
5976 Heisley Road
Mentor
Ohio
44060
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **1998-09-29**

Date: **2018-05-04**

Expiry Date: **2023-05-14**

...making excellence a habit.™

Page 1 of 1

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.