

EC Certificate - Full Quality Assurance System

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

No. CE 668821
Issued To: **Surgical Innovations Limited**
Clayton Wood House
6 Clayton Wood Bank
Leeds
LS16 6QZ
United Kingdom

In respect of:

The design, development and manufacture of:

- **Sterile laparoscopic instruments: band positioning device, device used for closure of tissues, wounds, hernias, and fat/tissue retraction; single use scissors and graspers; laparoscopic port access system; monopolar electrode device**
- **Non-sterile: laparoscopic reusable handles and graspers; laparoscopic reusable retraction device; laparoscopic port access system**

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: **2017-11-20**

Date: **2020-04-20**

Expiry Date: **2023-03-18**

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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.

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Supplementary Information to CE 668821

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
45631 – handle	Logic Laparoscopic Instrument System	To cut, dissect, manipulate and/or cauterize various tissues during endoscopy/ laparoscopy, general, vascular, gynecological and thoracic surgical procedures.
62061 – insert (RU)	Logi Laparoscopic Instrument System	
61875 – insert (SU)	Logi Laparoscopic Instrument System	
Class IIa		
MD 0106	Laparoscopic instruments for port access	---
MD 0106	Laparoscopic instruments for retraction	---
MD 0106	Laparoscopic instrument for gastric band positioning	---

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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Brandauer 235 Bridge Street Birmingham B19 2YU United Kingdom	Crucial Supplier
Claro Precision Engineering Manse Lane Industrial Estate Knaresborough North Yorkshire HG5 8LF United Kingdom	Crucial Supplier
Colour Anodising Horland Street Radcliffe Manchester M26 2RH United Kingdom	Crucial Supplier

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Subcontractor:	Service(s) supplied
Dawson Precision Components Greenfield Lane Shaw Oldham OL2 8QP United Kingdom	Crucial Supplier
Excel Mould Ltd. 3/F., Flourish Industrial Building no. 33 Sheung Yee Road Kowloon Bay Kowloon Hong Kong	Crucial Supplier
Kirkstall Precision Units G4, G5 and G6 Wyther Lane, Wyther Park Industrial Estate Leeds West Yorkshire LS5 3AR United Kingdom	Crucial Supplier

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Subcontractor:	Service(s) supplied
Nolato Magyarország Kft. 9200 Mosonmagyaróvár Jánossomorjai u. 3. Hungary	Manufacture
Nolato MediTech AB Medicingatan 4 SE-242 21 Hörby Sweden	Manufacture
Riverside Medical Packaging Company Ltd Newmarket Drive Derby DE24 8SW United Kingdom	Packaging

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Subcontractor:	Service(s) supplied
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	Gamma Irradiation
Synergy Health Sterilisation UK Ltd Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	Gamma Irradiation
T HALLIDAY Engineering Ltd T/A Kay Engineering 112A Windmill Road Sunbury On Thames Middlesex TW16 7HB United Kingdom	Crucial Supplier

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
20 November 2017	8689510	First issue. Transfer from another notified body.
26 April 2018	8926489	Certificate renewal, scope clarification and correction, scope removal of "reusable scissors".
14 February 2019	8889507	Traceable to NB 0086.
Current	3118126	Administrative change to correct typographical error in Surgical Innovations address. Added new sterilization site Synergy Health Daventry. Addition of supplementary table.

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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.