

# EC Certificate - Full Quality Assurance System

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

**No.****CE 665498**

## Issued To:

**Microline Surgical, Inc.  
50 Dunham Road, Suite 1500  
Beverly  
Massachusetts  
01915  
USA**

## In respect of:

**Design, development and manufacture of active laparoscopic surgical handpieces, sterile cautery tips, non-sterile cautery probes, sterile and non-sterile scissor tips, sterile and non-sterile dissector tips and grasper tips, sterile atraumatic grasper tips, sterile clips and non-sterile clip appliers.**

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: **2017-06-05**Date: **2020-07-30**Expiry Date: **2024-05-26**

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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 665498

Issued To:

**Microline Surgical, Inc.**  
**50 Dunham Road, Suite 1500**  
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NBOG Code(s)	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 1104	Non-sterile Clip Applier Handpieces – Reusable Multi-Fire Endoscopic	N/A for class IIa
<b>Class IIb</b>		
MD 1104 MD 0204 MDS 7006	Sterile Clip Disposable Cartridge	Clip Cartridge is indicated for occluding and ligating vessels, ducts, tracts and other tubular structures during laparoscopic and general surgical procedures.
MD 1104	Non-sterile Handpieces, 5mm Reusable Monopolar	Handpieces and tips are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.
MD 1104 MDS 7006	Sterile Disposable Scissor Tips	The single patient use disposable tips are to be used with the Laparoscopic Hand pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.

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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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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
MD 1104	Non-sterile Reusable Scissor Tips	ReNew Reusable Scissor Tips are to be used with the reusable Laparoscopic instrument hand pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.
MD 1104 MDS 7006	Sterile Disposable Grasper and Dissector Tips	Single patient disposable tips are to be used with the Laparoscopic Hand pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures
MD 1104 MDS 7006	Sterile Atraumatic Grasper Tips	Single patient disposable tips are to be used with the Laparoscopic Hand pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures
MD 1104	Non-sterile Reusable Grasper and Dissector Tips	to be used with the reusable Laparoscopic instrument hand pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.

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Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
MD 1104	Non-sterile 5mm Laparoscopic Cautery Probes	The electrocautery Probe Handpiece and Electrode Tips are intended to cauterize tissues in endoscopic and laparoscopic surgical procedures.
MD 1104 MDS 7006	Sterile 5mm Laparoscopic Cautery Tips	The electrocautery Probe Handpiece and Electrode Tips are intended to cauterize tissues in endoscopic and laparoscopic surgical procedures.

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## List of Significant Subcontractors

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

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Date: **2020-07-30**  
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**50 Dunham Road, Suite 1500**  
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**Massachusetts**  
**01915**  
**USA**

**Subcontractor:**

**Service(s) supplied**

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Isomedix Operations, Inc.  
3459 South Clinton Avenue  
South Plainfield  
New Jersey  
07080  
USA

**ETO Sterilization**

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MDSS GmbH  
Schiffgraben 41  
Hannover  
30175  
Deutschland

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

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 Date: **2020-07-30**  
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**01915**  
**USA**

Date	Reference Number	Action
05 June 2017	8651082	First issue. Transfer from another Notified Body.
08 February 2019	8786985	Traceable to NB 0086.
21 November 2019	8888883	Subcontractor Parker Hannifin Corporation location update, Subcontractor Isomedix location update, addition of supplementary production information table. Subcontractor Linemaster Switch Corporation added.
Current	3220236	Certificate Renewal. Change in scope. Former scope "Design, development and manufacture of active laparoscopic surgical instruments, sterile and non-sterile scissor, grasping and dissecting tips; sterile and non-sterile clip appliers, sterile ligating clips; sterile cautery forceps, sterile and non-sterile thermal ligation shears (Including power supply and footswitch)". Current scope "Design, development and manufacture of active laparoscopic surgical handpieces, sterile cautery tips, non-sterile cautery probes, sterile and non-sterile scissor tips, sterile and non-sterile dissector tips and grasper tips, sterile atraumatic grasper tips, sterile clips and non-sterile clip appliers". Withdraw of devices: Power Supply and footswitch, Thermal cautery disposable forceps, Thermal Ligating Shears.

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Date	Reference Number	Action
		Removal of subcontractors: Parker Hannifin Corporation 1201 East 86th Place Merrillville, Indiana 46410, USA. Linemaster Switch Corporation 29 Plaine Hill Road, Woodstock, CT 06281, USA. GDM Electronic & Medical 2070 Ringwood Avenue, San Jose CA 95131, USA. Isomedix Operations, Inc. 2500 Commerce Drive, Libertyville, IL USA 60048.