

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 723691 R000

Manufacturer: Microline Surgical, Inc.

Address:

50 Dunham Road, Suite 1500
Beverly
Massachusetts
01915
USA

Single Registration Number: US-MF-000009811

EU Authorised Representative: Medical Device Safety Service GmbH (MDSS)

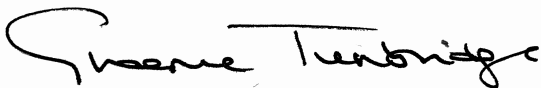
Address:

Schiffgraben 41
Hannover
30175
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

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



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-09-07**

Date: **2022-08-16**

Expiry Date: **2026-09-06**

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Device Schedule: Class IIb devices

Class IIb, Implantable, Well-established technologies	Intended purpose
Sterile Clip Cartridge - Disposable	Clip Cartridges include clips which are implanted (WET)
Class IIb	Intended purpose
Thermal cautery disposable Forceps.	The devices are indicated for simultaneous cutting and cauterization of soft tissue during surgery and for cutting of natural and synthetic, non-metallic sutures during surgery.
Thermal Ligating Shears	The devices are indicated for simultaneous cutting and cauterization of soft tissue during surgery and for cutting of natural and synthetic, non-metallic sutures during surgery.
Laparoscopic Instruments: Disposable Scissor Tips, Disposable Grasper Tips, Atraumatic Grasper Tips, Disposable Dissector Tips	The ReNew single patient use disposable tips are to be used with the ReNew Laparoscopic Hand Pieces and they are indicated for cutting, grasping, dissecting and coagulation of tissue in endoscopic and laparoscopic surgical procedures.
Laparoscopic Instruments: Reusable Scissor Tips, Reusable Dissector Tips, Reusable Grasper Tips	ReNew Reusable Laparoscopic Instrument Tips are intended to be used with ReNew Reusable Laparoscopic Instrument Handpieces, and are indicated for cutting, grasping, dissecting, and coagulation of tissue in endoscopic and laparoscopic surgical procedures.
Universal Power Supply	The UPS is intended for use only with Microline Cautery Instruments and the PowerPack™ Dual Control Footswitch for the simultaneous cutting and cauterization of soft tissue during surgery.
Dual Control Footswitch	The PowerPack Dual Control Footswitch is intended for use only with Microline Cautery Instruments and the UPS for the simultaneous cutting and coagulation of soft tissue during surgery.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Laparoscopic Instruments: Handpieces, Reusable Monopolar	Class IIa
Non-sterile Clip Applier Handpieces - Reusable Multi-Fire Endoscopic	Class IIa



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-09-07	3141858	Issued
Current	3719089	Supplemented – Addition of M/L-10 Clips and Appliers devices



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

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 723691 R000

Date: 2022-08-16

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Isomedix Operations Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	ETO Sterilization
Isomedix Operations, Inc. 2500 Commerce Drive Libertyville IL 60048 United States of America	Radiation (Gamma Sterilization)

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