

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)

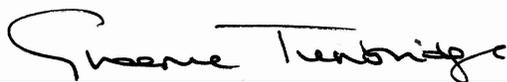
Address:

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Global Regulatory & Quality

First Issue Date: **2021-09-07**

Current Issue Date: **2024-10-04**

Starting Validity Date: **2024-10-04**

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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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
2022-08-16	3719089	Supplemented – Addition of M/L-10 Clips and Appliers devices
Current	30232800	Amended – Addition of subcontractor for sterilization. Amended – Removal of critical subcontractor and crucial supplier pages from certificate.

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