

EU Quality Management System Certificate

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

MDR 769661 R000

Manufacturer: Symmetry Surgical, Inc.

Address:

3034 Owen Drive
Antioch
Tennessee
37013
USA

Single Registration Number: US-MF-000024174

EU Authorised Representative: Emergo Group

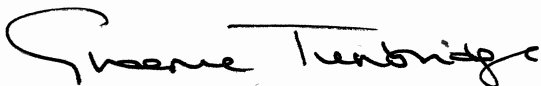
Address:

Westervoortsedijk 60
6827 AT Arnhem
Netherlands

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: **2024-08-23**

Current Issue Date: **2025-03-26**

Starting Validity Date: **2025-03-26**

Expiry Date: **2029-08-22**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Electrocautery Systems	Bovie Cautery Devices are used for stopping small bleeders in hemostasis. The high temperature Cauteries with a loop tip are used for stopping small bleeders in diffuse hemostasis and other similar uses where high temperature and loop tip are required. The low temperature Cauteries with a fine tip are used for pinpoint hemostasis and other similar uses where low temperature and a fine tip are required.
Electrosurgical Generators	Intended for cutting, coagulation, ablation of tissue.
Suction Coagulators	Coagulating tissue and removing fluid and debris from surgical site.
Electrosurgical Electrodes (sterile)	Coagulating tissues at the surgical site.
Electrosurgical Handpieces (Pencil and switchpens)	Coagulating tissues at the surgical site.
Electrosurgical Sterile Bipolar and Monopolar Forceps	Cutting and coagulation of tissue.
Electrosurgical Electrodes (nonsterile, end user sterilized)	Used in conjunction with electrosurgical hand piece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels/soft tissues.
Bovie footswitches	Activation of the RF output on Electrosurgical Generators.
Return Electrode Cables and Pads	Return Electrode Cables and Pads are used in monopolar surgery for the safe return of generator current back to the generator.

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

Device(s)	Risk Classification
Eye Bubble	Class Is
Tubes, Adapters and Hoses	Class Is
Sheath	Class Is
Sharp Instruments, Reusable	Class Ir
Suture Supporting Instruments, Reusable	Class Ir
Surgical Instruments, Reusable	Class Ir

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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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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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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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
2024-08-23	3662351	Issued
2024-09-24	30268770	Supplemented - Addition of Electrocautery Systems and Electrosurgical Generators.
2024-12-10	30317302	Supplemented - Addition of Suction Coagulators, Electrosurgical Handpeices, Electrosurgical Sterile Bipolar and Monopolar Forceps, Electrosurgical Electrodes (sterile and end-user sterilized) and Bovie footswitches to Device Schedule Class IIb.
Current	30400926	Supplemented – Addition of Return Electrodes to device schedule Class IIb

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