# 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.<br>The high temperature Cauteries with a loop tip are used for stopping small bleeders in diffuse hemostasis and other similar uses were 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.<br>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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### 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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