

DECLARATION OF CONFORMITY (DoC) - Section 7
MEDICAL DEVICE REGULATION (EU) 2017/745 (Annex IV)

DOC TF-E002
Rev F



MANUFACTURER: Symmetry Surgical Inc.
3034 Owen Drive
Antioch, TN 37013 USA
SRN #: US-MF-000024174

MEDICAL DEVICE: Bovie Cauteries and Replaceable Tips
TF-E002

CLASSIFICATION IN ACCORDANCE WITH ANNEX VIII: Class IIb, Rule 9.

CONFORMITY ASSESSMENT ROUTE: *Add Conformity Assessment Route(s) i.e.,
EU 2017/745 Annex IX Chapter I and III*

Symmetry Surgical declares that the above-mentioned products meet the provision of the following EU Legislation:
* Medical Device Regulation (EU) 2017/745

The EU Declaration of Conformity is issued under the sole responsibility of Symmetry Surgical.

NOTIFIED BODY: BSI Product Services
BSI Group, Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, Netherlands

IDENTIFICATION NUMBER: 2797

(EC) CERTIFICATE(S): MDR 769661 R000

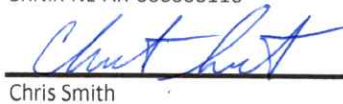
BS EN ISO13486:2016: BSI MDSAP - Certification #: MDSAP 691125

COMMON SPECIFICATIONS: *Not applicable to these devices*



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SIGNATURE:

 *April 17, 2025*

DATE

Chris Smith
REGULATORY AFFAIRS Director
For, and on behalf of,
Company: Symmetry Surgical Inc.
Place of Issuance: Antioch, TN

Product List

Last updated by:	Chris Smith
Product	Cauteries
Family/Group:	

Date: 12/10/2024

TD Reference: TF-E002

P/N	DESCRIPTION	CLASS	RULE	BASIC UDI	INTENDED USE
AA05	CAUTERY HIGH TEMPERATURE 2" EXTENDED SHAFT LOOP TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA17	CAUTERY HIGH TEMP FINE TIP 2" EXTENDED SHAFT (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA09	CAUTERY HIGH TEMPERATURE LOOP TIP 5" EXTENDED SHAFT (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA02	CAUTERY LOW ADJUST-A-TEMP™ FINE TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA29	CAUTERY HIGH TEMPERATURE MICRO ELONGATED TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA27	CAUTERY HIGH TEMPERATURE MICRO LOOP TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA25	CAUTERY HIGH TEMPERATURE MICRO FINE TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA11	CAUTERY HIGH TEMP ADJUST-A-TEMP™ FINE TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA90	CAUTERY LOW TAMPERATURE MICRO FINE TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA00	CAUTERY LOW TEMPERATURE FINE TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA04	CAUTERY LOW TEMPERATURE ELONGATED FINE TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA01	CAUTERY HIGH TEMPERATURE FINE TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA03	CAUTERY HIGH TEMPERATURE LOOP TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA21	CAUTERY HIGH TEMPERATURE ELONGATED TIP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA00X	CAUTERY LOW TEMPERATURE FINE TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA01X	CAUTERY HIGH TEMPERATURE FINE TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.

AA03X	CAUTERY HIGH TEMPERATURE LOOP TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA04X	CAUTERY LOW TEMPERATURE ELONGATED FINE TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA05X	CAUTERY HIGH TEMPERATURE 2" EXTENDED SHAFT LOOP TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA17X	CAUTERY HIGH TEMP FINE TIP 2" EXTENDED SHAFT (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
AA21X	CAUTERY HIGH TEMPERATURE ELONGATED TIP (ORIGINAL)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
HIT0	POWER HANDLE LOW-TEMP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
HIT1	POWER HANDLE HIGH-TEMP (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
DEL1	CHANGE - A - TIP™ DELUXE HIGH TEMPERATURE CAUTERY KIT (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
DELO	CHANGE-A-TIP™ DELUXE LOW TEMPERATURE CAUTERY KIT (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
DEL2	CHANGE - A - TIP™ DELUXE HI-LO TEMPERATURE CAUTERY KIT (SNAP)	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H100	REPLACEABLE LOW-TEMP FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H101	REPLACEABLE FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H104	REPLACEABLE FINE TIP WITH ADHESIVE	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H109	REPLACEABLE LOOP TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H110	REPLACEABLE FINE TIP ELONGATED	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H112	REPLACEABLE 2" FLEX LOOP TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H101-ADH	REPLACEABLE 2" FLEX FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H105	REPLACEABLE 5" LOOP TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H106	REPLACEABLE CONTRA ANGLE FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.

H103	REPLACEABLE CIRCULAR TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H111	REPLACEABLE 6" FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
H121	REPLACEABLE ELONGATED TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
20-HM-1000	SHIPPERT CAUTERY HIGH TEMP FINE TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
20-HM-2000	CAUTERY HIGH TEMP LOOP TIP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.
SOSCAA90	PRIVATE LABEL SURGICAL & OPHTHALMIC SUPPLIES CAUTERY MICRO LO-TEMP	IIb	9	0887482Cautery94	Bovie® Cautery Devices are used for stopping small bleeders in hemostasis.

