

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

444

MANUFACTURER: Symmetry Surgical Inc.

3034 Owen Drive Antioch, TN 37013 USA SRN #: US-MF-000024174

MEDICAL DEVICE: Bovie Diagnostic Lights and Pen Lights

Technical Documentation Number (TF-E007-4)

CLASSIFICATION IN ACCORDANCE WITH ANNEX VIII: Class I Non-Sterile, Non-Measuring, or Non-Reusable

Symmetry Surgical declares that the above-mentioned products meet the provision of the following EU legislation:

- ■Medical Devices Regulation (EU) 2017/745
- ●RoHS Directive 2011/65/EU

NOTIFIED BODY: Self- Declaration

IDENTIFICATION NUMBER: N/A

(EC) CERTIFICATE(S): N/A

BS EN ISO13486:2016: *BSI MDSAP - Certification #: 704538*

HARMONIZED STANDARDS/

COMMON SPECIFICATIONS: *IEC 60601-1*

Trade Names: Specialty Lights, Woods Lights, Cobalt Pens, Penlights

EC REP Emergo Group

EUROPEAN REPRESENTATIVE: Westervoortsedijk 60 6827 AT Arnhem

The Netherlands

SRN#: NL-AR-00000116

SIGNATURE: Chris Smith October 11, 2024

NAME DATE

Title: Sr. Director of Regulatory Affairs Company: Symmetry Surgical Inc.



Product List

Last updated by: Chris Smith	Date: 10/10/2024	
Product Bovie Diagnostic Lights and Pen Lights Family/Group:	TD Reference:	TF-E007-4

P/N	DESCRIPTION	CLASS	RULE	BASIC UDI	INTENDED USE
6802	Bovie Diagnostic Lights	ı	13	0887482Fluoro-DotVN	portable light used in conjunction with fluorescein dye to find foreign matter in the eye
UV59	Bovie Diagnostic Lights	ı	13	0887482Light48	portable light used in conjunction with fluorescein dye to find foreign matter in the eye
6303	Penlight; Cobalt 3 Per Pack	I	13	0887482Light48	aid for visualization
6666	Penlight Disposable; 6 Per Pack	I	13	0887482Light48	aid for visualization
66RN	Penlight Disposable; 6 Per Pack	I	13	0887482Light48	aid for visualization



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Last updated by:	Chris Smith	Date:	10/11/2024
Product	Bovie Diagnostic Lights and Pen Lights		
Family/Group:	bovie Diagnostic Lights and Pen Lights	TD Reference:	TF-E007-4

Rev/Date	Description of change eMDR under Symmetry Surgical	Updated by Not Applicable
А	eMDR under Symmetry Surgical	Not Applicable