DECLARATION OF CONFORMITY (DoC) - Section 7

EUROPEAN MEDICAL DEVICE REGULATION (EU) 2017/745 (Annex IV) (eMDR)

MANUFACTURER: Bovie Medical Corporation
5115 Ulmerton Road
Clearwater, FL 33760 USA
SRN #: (Pending)

MEDICAL DEVICE: Bovie Diagnostic Lights
Technical Documentation Number (DOC 008)

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

Bovie Medical 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: *Intertek MDSAP - Certification #: 01101146*

HARMONIZED STANDARDS/ COMMON SPECIFICATIONS: *IEC 60601-1*

Trade Names: *Specialty Lights, Woods Lights*

EC REP

EUROPEAN REPRESENTATIVE:
(31) (0) 70 345-8570

Emergo Europe B.V.
Prinsessegracht 20
2514 AP The Hague
The Netherlands
SRN#: NL-AR-000000116

SIGNATURE: May 21, 2021

NAME DATE

Title: Sr. Director of Regulatory Affairs
Company: Bovie Medical Corporation
Place of Issuance: Antioch, TN

Product List

Last updated by: Chris Smith

Date: 5/21/2021

Product Family/Group: Bovie Diagnostic Lights

TD Reference: DOC 008

P/N	DESCRIPTION	CLASS	RULE	BASIC UDI	INTENDED USE
6802	Bovie Diagnostic Lights	I	13	06071510LightsYV	portable light used in conjunction with fluorescein dye to find foreign matter in the eye
UV59	Bovie Diagnostic Lights	I	13	06071510LightsYV	portable light used in conjunction with fluorescein dye to find foreign matter in the eye

Product List

Last updated by:	Chris Smith	**Date:**	5/21/2021
Product Family/Group:	Bovie Diagnostic Lights	**TD Reference:**	DOC 008

Rev/Date	Description of change	Updated by
A-J	Bovie Medical Quality System (Acquired business)	Not Applicable
K	New format and to accommodate eMDR Requirements	Chris Smith
L	Revised to accommodate input from EMERGO	Chris Smith
M	Revised to accommodate input from EMERGO ON eMDR	Chris Smith