## 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: Chris Hunt 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 |