Bovie®

Declaration of Conformity

"We hereby declare that the mentioned devices comply with LVFS 2003:11 as amended by LVFS 2009:18 transposing European Medical Devices Directive 93/42/EEC as amended by 2007/47/EC."

MANUFACTURE'S NAME	**Bovie Medical Corporation**
BUSINESS ADDRESS:	5115 Ulmerton Road Clearwater, Florida 33760, USA
IDENTIFICATION OF THE DEVICE:	**Bovie Diagnostic Lights**
DECLARATION OF CONFORMITY NUMBER:	008
REVISION :	J
ESSENTIAL REQUIREMENTS CHECK LIST:	ER-99001
DEVICE MASTER RECORD INDEX (DMRI):	DMRI-8074, DMRI-10080, DMRI-10082, DMRI-0084, DMRI-0086
CATALOG NUMBER:	6802, UV59
CONFORMITY ASSESSMENT ROUTE: **EC CERTIFICATE NUMBER:**	Annex VII (EC Declaration of Conformity) Not Applicable
MANUFACTURING SITE:	Bovie Medical Corporation 5115 Ulmerton Road Clearwater, Florida 33760, USA
CLASSIFICATION OF THE DEVICE:	Annex IX (III), Rule 12, All other active devices are in Class I
NOTIFIED BODY:	Intertek Semko AB (0413) Torshamnsgatan 43, Box 1103 SE-164 22 Kista SWEDEN
STANDARDS: EN 60601-1:2006/A1:2013, EN ISO 15223-1: 2016, EN-1041:2008, EN ISO 14971:2012, EN 60601-1-2:2015, EN ISO 13485:2016	

EC Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 PA The Hague
The Netherlands

David Ceretti — 6-17-2019

David Ceretti — **Date**
Regulatory Affairs Manager

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