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 Nerve Locators**
DECLARATION OF CONFORMITY NUMBER:	003
REVISION :	K
ESSENTIAL REQUIREMENTS CHECK LIST:	ER-98003
DEVICE MASTER RECORD INDEX (DMRI):	DMRI-10171
CATALOG NUMBER:	0003Y
CONFORMITY ASSESSMENT ROUTE: **EC CERTIFICATE NUMBER:**	Annex II (Full Quality Assurance System) 41312698-01
MANUFACTURING SITE:	Bovie Medical Corporation 5115 Ulmerton Road Clearwater, FL 33760, USA
CLASSIFICATION OF THE DEVICE:	IIa, Rule 6, All surgically invasive devices intended for transient use are in Class IIa; Rule 10 Acitive devices intended for diagnosis are in Class IIa if they are intended to supply energy which will be absorbed by the except for the devices used to illuminate the patients's body, in the visible spectrum.
NOTIFIED BODY:	Intertek Semko AB (0413) Torshamnsgatan 43, Box 1103 SE-164 22 Kista SWEDEN
STANDARDS: EN 60601-1:2006/A1:2013, EN ISO 10993-1:2009, EN ISO 15223-1: 2016, EN-1041 (2008), EN ISO 14971:2012, EN 60601-1-6:2010 , EN ISO 11135-1:2014, EN ISO 11607-2:2006, EN ISO 11607-1:2009, EN ISO 10993-7:2008, EN 62366:2008	

EC Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 PA The Hague
The Netherlands

6-17-2019

David Ceretti — **Date**
Regulatory Affairs Manager

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