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 Cauteries (snap design) and Replaceable Tips**
DECLARATION OF CONFORMITY NUMBER:	001
REVISION :	Q
ESSENTIAL REQUIREMENTS CHECK LIST:	ER-13001
DEVICE MASTER RECORD INDEX (DMRI):	DMRI_12000_23, DMRI-S30115_4, DMRI-S30116_4, DMRI-DEL2_5, DMRI-S30064_11, DRMI-S30066_8, DMRI-S30067_5, DRMI-S30068_2, DMRI-S30112_3, DMRI-S30113_3
CATALOG NUMBER:	SOSCAA90, AA01, AA03, AA05, AA17, AA21, AA25, AA27,, AA29, 0231, 0233, 0235, 20-HM-1000, 20-HM-2000AA00, AA04, AA90, HIT0, HIT1, DEL0, DEL1, DEL2, HISL, CH05, H100, H101, H103, H104, H105, H106, H109, H110, H111, H112, H121, H101-ADH
CONFORMITY ASSESSMENT ROUTE: **EC CERTIFICATE NUMBER:**	Annex II (Full Quality Assurance) 41312698-01
MANUFACTURING SITE:	Bovie Medical Corporation 5115 Ulmerton Road Clearwater, Florida 33760, USA
CLASSIFICATION OF THE DEVICE:	Annex IX, (III), IIb, Rule 9, all active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.
NOTIFIED BODY:	Intertek Semko AB (0413) Torshamnsgatan 43, Box 1103 SE-164 22 Kista SWEDEN
STANDARDS: EN 60601-1:2006/A1:2013, EN ISO 14971:2012, EN 62366:2008, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 13485:2016, EN ISO 10993-1:2009, EN 60601-1-2:2015, EN 60601-2-2:2009; EN 60601-1-6:2010, EN ISO 11135:2014, EN ISO 11607-2:2006, EN ISO 11607-1:2009	

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Bovie®

EC Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 PA The Hague
The Netherlands

6-19-2019

David Ceretti
Regulatory Affairs Manager

Date

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