Declaration of Conformity

"We hereby declare that the mentioned devices comply with European Medical Devices Directive 93/42/EEC as amended by 2007/42/EC."

MANUFACTURER'S NAME	**Bovie Medical Corporation**
BUSINESS ADDRESS:	5115 Ulmerton Road Clearwater, Florida 33760, USA
IDENTIFICATION OF THE DEVICE:	Electrosurgical Electrodes
DECLARATION OF CONFORMITY NUMBER:	011
REVISION:	AA
ESSENTIAL REQUIREMENTS CHECK LIST:	ER-99004 Sterile
DEVICE HISTORY FILE/PROJECT NUMBER:	DHF-Device History Index for Disposable electrodes, Device History Index for Loop Electrodes, Device History Index Tungsten Loops, Needles and Arthroscopic Electrodes & CMP-00003
DEVICE MASTER RECORD INDEX (DMRI):	DMRI-S30038_4, DMRI-13006_32, DMRI-S30082_8, DMRI-S30035_10, DMRI-S30032_21, DMRI-13002_30, DMRI-13039_16, DMRI-13038_19, DMRI-S30098_1, DMRI-S30042_6, DMRI-13000M_38, DMRI-S30046_8, DMRI-S30057_4, DMRI_S30130_0, DMRI_S30131_0, DMRI_S30132_0
CATALOG NUMBERS	See Attached
CONFORMITY ASSESSMENT ROUTE: **EC CERTIFICATE NUMBER:**	Annex II excluding section 4 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 potential hazardous way, taking account of the nature, the density and the 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 ISO 15223-1:2016, EN 1041:2008, EN ISO 13485:2016, EN ISO 10993-1:2009, EN 60601-2-2:2009, EN ISO 11135-1:2007, EN ISO 11607-2:2006, EN ISO 11607-1:2009, EN ISO 10993-7:2008

EC Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Bovie

Chuck Lutt — June 13, 2022

Name — **Date**

Regulatory Affairs Manager/Designee
Symmetry on behalf of Bovie Medical

Product List Attached

The following product catalog numbers are included in this Declaration of Conformity:

Catalog Number	Description	Classification /Rule
ES01 ES02 ES03 ES04 ES06 ES07 ES18 ES20 ES21 ES37 ES38 ES39 ES40 ES50 ES54 ES55 ES58 ES59 ES71 809315 809316 809317 809318 809319 809335 809337 809338 809339, E15646, E15644,	Electrodes	IIb/Rule 9
ES08 ES09 ES10 ES11 ES12 ES13 ES14 ES15 ES16 ES31 ES41 ES42 ES43 ES44 ES45 ES46 ES47 ES48 ES49 ES51 ES52 ES53 ESLK E15596, E15606, E15616, E15626, E15594, E15604, E15614, E15624	Loop Electrodes	IIb/Rule 9
ES60 ES61 ES62 ES63 ES61HS A834 E16512 E16514	Tungsten Needle Electrodes	IIb/Rule 9
ES22 ES23 ES24 ES25 ES26	Tungsten Loop Electrodes	IIb/Rule 9
ES22-8 ES23-8 ES24-8 ES25-8 ES26-8	Tungsten Loop Electrodes (.008 wire)	IIb/Rule 9
ES01T ES02T ES03T ES04T ES06T ES07T ES18T ES20T ES21T ES37T ES38T ES39T ES40T ES50T ES54T ES55T ES56T ES57T ES58T ES59T ES0012AMEU, ES0014AMEU, ES0012AEU, ES0013EU, ES0014EU, ES0016EU	Coated Electrodes	IIb/Rule 9
A805 A807 A807DE	Dermal Tip Electrodes	IIb/Rule 9
AR00 AR01 AR02 AR03	Arthroscopic Electrodes	IIb/Rule 9
LL06 LC04 LB02 LS05 LJ07 LH08 LH01 LN03	Laparoscopic Electrodes	IIb/Rule 9