Bovie Medical Corporation
5115 Ulmerton Road
Clearwater,
Florida 33760

19 September 2023

MDD Extension Confirmation Letter - Bovie Medical – 01
Reference: *41312689-01* Annex II
41313069-02 Annex V

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, BSi, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2797 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Bovie Medical Corporation
5115 Ulmerton Road
Clearwater,
Florida 33760

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a

Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Products included in the Product List to Certificate No: 41312698-01

Product category	Type/Model designation	Class
Surgical Lights	ST05	IIa
	ST10	IIa
	ST15	IIa
Nerve Locators	0003Y	IIa
Ophthalmic Burrs	0001	IIa
	0011	IIa
	0012	IIa
	AB01	IIa
	AB05	IIa
Ophthalmic Power Handle	0010	IIa
Cauteries		
High Temperature Cauteries		
	AA01X	IIb
	AA03X	IIb
	AA05X	IIb
	AA09	IIb
	AA11	IIb
	AA17X	IIb
	AA21X	IIb
High Temperatures Snap	AA01	IIb
Design Cauteries	AA03	IIb
	AA05	IIb
	AA17	IIb
	AA21	IIb
	20-HM-1000	IIb
	20-HM-2000	IIb
	AA25	IIb
	AA27	IIb
	AA29	IIb
Ophthalmic Cauteries		
	AA00X	IIb

Product category	Type/Model designation	Class
	AA02	IIb
	AA04X	IIb
	SOSCAA04	IIb
	SOSCAA90	IIb
Ophthalmic Snap Design	AA00	IIb
Cauteries	AA04	IIb
	AA90	IIb
Electrosurgery	CH05	IIb
Accessories Replacement	H100	IIb
Tips	H101	IIb
	H101-ADH	IIb
	H103	IIb
	H104	IIb
	H105	IIb
	H106	IIb
	H109	IIb
	H110	IIb
	H111	IIb
	H112	IIb
	H121	IIb
Replacement Tip Kits	DEL0	IIb
	DEL1	IIb
	DEL2	IIb
	HIT0	IIb
	HIT1	IIb
Generators	DERM 942 A942	IIb
	Bantam/PRO A952	IIb
	A1250S	IIb
	A2350	IIb
	A3350	IIb
	IDS-210	IIb
	IDS-310	IIb
	DERM 102	IIb
	EM010 High Frequency Electrosurgical Generator	IIb

Product category	Type/Model designation	Class
Electrosurgery Pencils	A901	IIb
	A902	IIb
	ESP1	IIb
	ESP1H	IIb
	ESP1HN	IIb
	ESP1HS	IIb
	ESP1N	IIb
	ESP6	IIb
	ESP6H	IIb
	ESP6HN	IIb
	ESP6HS	IIb
	ESP6N	IIb
	ESP7	IIb
	ESP7H	IIb
	ESP7HN	IIb
	ESP7HS	IIb
	ESP7N	IIb
	ESPH	IIb
	ESPR	IIb
	ESPR2	IIb
	ESSP	IIb
	ESP1T	IIb
	ESP1TN	IIb
	ESP6T	IIb
	ESP6TN	IIb
Electrodes; Standard	ES01	IIb
	ES02	IIb
	ES03	IIb
	ES04	IIb
	ES06	IIb
	ES07	IIb
	ES18	IIb
	ES20	IIb
	ES21	IIb
	ES37	IIb
	ES38	IIb
	ES39	IIb
	ES40	IIb

Product category	Type/Model designation	Class
	ES50	IIb
	ES54	IIb
	ES55	IIb
	ES58	IIb
	ES59	IIb
	E15644	IIb
	E15646	IIb
Electrodes; Loop	ES08	IIb
	ES09	IIb
	ES10	IIb
	ES11	IIb
	ES12	IIb
	ES13	IIb
	ES14	IIb
	ES15	IIb
	ES16	IIb
	ES31	IIb
	ES41	IIb
	ES42	IIb
	ES43	IIb
	ES44	IIb
	ES45	IIb
	ES46	IIb
	ES47	IIb
	ES49	IIb
	ES51	IIb
	ES52	IIb
	ES53	IIb
	ESLK	IIb
	E15596	IIb
	E15606	IIb
	E15616	IIb
	E15626	IIb
	E15594	IIb
	E15604	IIb
	E15614	IIb
	E15624	IIb
	ES09-NS	IIb

Product category	Type/Model designation	Class
	ES13-NS	IIb
	ES42-NS	IIb
	ES53-NS	IIb
Tungsten Needle	A834	IIb
Electrodes	ES60	IIb
	ES61	IIb
	ES61HS	IIb
	ES62	IIb
	ES63	IIb
	E16512	IIb
	E16514	IIb
Tungsten Needle	ES60R	IIb
Reusable Electrodes	ES62R	IIb
Tungsten Loop Electrodes	ES22	IIb
	ES23	IIb
	ES24	IIb
	ES25	IIb
	ES26	IIb
	ES14-NS	IIb
	ES15-NS	IIb
	ES16-NS	IIb
Tungsten Loop Electrodes	ES22R	IIb
Reusable	ES23R	IIb
	ES24R	IIb
	ES25R	IIb
	ES26R	IIb
Tungsten Loop Electrodes	ES22-8	IIb
(.008 Wire)	ES23-8	IIb
	ES24-8	IIb
	ES25-8	IIb
	ES26-8	IIb
Reusable Electrodes	A830	IIb
	A831	IIb
	A832	IIb
	A833	IIb
	A834	IIb
	A836	IIb
	ES01R	IIb

Product category	Type/Model designation	Class
	ES02R	IIb
	ES03R	IIb
	ES04R	IIb
	ES06R	IIb
	ES07R	IIb
	ES08R	IIb
	ES09R	IIb
	ES10R	IIb
	ES11R	IIb
	ES12R	IIb
	ES13R	IIb
	ES14R	IIb
	ES15R	IIb
	ES16R	IIb
	ES18R	IIb
	ES20R	IIb
	ES21R	IIb
	ES31R	IIb
	ES41R	IIb
	ES42R	IIb
	ES43R	IIb
	ES44R	IIb
	ES45R	IIb
	ES46R	IIb
	ES47R	IIb
	ES49R	IIb
	ES51R	IIb
	ES52R	IIb
	ES53R	IIb
	ES55R	IIb
	ES58R	IIb
Coated Electrodes	BVX02T	IIb
	BVX03T	IIb
	BVX06T	IIb
	BVX07T	IIb
	BVX20T	IIb
	BVX21T	IIb
	BVX37T	IIb

Product category	Type/Model designation	Class
	BVX38T	IIb
	BVX39T	IIb
	BVX40T	IIb
	BVX50T	IIb
	BVX54T	IIb
	BVX56T	IIb
	BVX57T	IIb
	ES01T	IIb
	ES02T	IIb
	ES03T	IIb
	ES04T	IIb
	ES06T	IIb
	ES07T	IIb
	ES0013EU	IIb
	ES0014EU	IIb
	ES0016EU	IIb
	ES18T	IIb
	ES20T	IIb
	ES21T	IIb
	ES37T	IIb
	ES38T	IIb
	ES39T	IIb
	ES40T	IIb
	ES50T	IIb
	ES54T	IIb
	ES55T	IIb
	ES56T	IIb
	ES57T	IIb
	ES58T	IIb
	ES59T	IIb
	ES65T	IIb
	ES0012AMEU	IIb
	ES0014AMEU	IIb
Electrodes (Coated; Blue; Non-Sterile)	ES01T-NS	IIb
	ES02T-NS	IIb
	ES03T-NS	IIb
	ES04T-NS	IIb
	ES06T-NS	IIb

Product category	Type/Model designation	Class
	ES07T-NS	IIb
	ES18T-NS	IIb
	ES20T-NS	IIb
	ES21T-NS	IIb
	ES37T-NS	IIb
	ES38T-NS	IIb
	ES39T-NS	IIb
	ES40T-NS	IIb
	ES50T-NS	IIb
	ES54T-NS	IIb
	ES55T-NS	IIb
	ES56T-NS	IIb
	ES57T-NS	IIb
	ES58T-NS	IIb
	ES59T-NS	IIb
	ES64T-NS	IIb
	ES65T-NS	IIb
	ES66T-NS	IIb
	ES67T-NS	IIb
	ES68T-NS	IIb
	ES69T-NS	IIb
	ES70T-NS	IIb
Dermal Tip Electrodes	A804	IIb
	A805	IIb
	A806	IIb
	A806DE	IIb
	A807	IIb
	A807DE	IIb
	Electrode Sharp Tip Non-Sterile 100/Box H10012	IIb
	Electrode Sharp Tip Sterile 50/Box H10008	IIb
	Electrode Blunt Angled Blade Non-Sterile 100/Box H10112	IIb
Arthroscopic Electrodes	AR00	IIb

Product category	Type/Model designation	Class
	AR01	IIb
	AR02	IIb
	AR03	IIb
	AR00-NS	IIb
	AR01-NS	IIb
	AR02-NS	IIb
Forceps	A820	IIb
	A821	IIb
	A822	IIb
	A823	IIb
	A824	IIb
	A825	IIb
	A826	IIb
	A827BP	IIb
	A827F	IIb
	A827V	IIb
	A840	IIb
	A841	IIb
	A842	IIb
	A843	IIb
	A844	IIb
	A845	IIb
Footswitch	A1203	IIb
	A1203W	IIb
	BV-1253B	IIb
	BV-1254B	IIb
	A803	IIb
Insulated Needle Electrode	ELD6B	IIb
Insulated Sclerotherapy	ELD42	IIb
Laparoscopic Electrodes	BVX-LL06-NS	IIb
	BVX-LC04-NS	IIb
	BVX-LB02-NS	IIb
	BVX-LS05-NS	IIb
	BVX-LJ07-NS	IIb
	BVX-LH08-NS	IIb
	BVX-LH01-NS	IIb
	BVX-LN03-NS	IIb
	LL06-NS	IIb

Product category	Type/Model designation	Class
	LC04-NS	IIb
	LB02-NS	IIb
	LS05-NS	IIb
	LJ07-NS	IIb
	LH08-NS	IIb
	LH01-NS	IIb
	LN03-NS	IIb
	LL06	IIb
	LC04	IIb
	LB02	IIb
	LS05	IIb
	LJ07	IIb
	LH08	IIb
	LH01	IIb
	LN03	IIb
	BVX-LL06	IIb
	BVX-LC04	IIb
	BVX-LB02	IIb
	BVX-LS05	IIb
	BVX-LJ07	IIb
	BVX-LH08	IIb
	BVX-LH01	IIb
	BVX-LN03	IIb
Laparoscopic Electrodes	BVX-LL06T-NS	IIb
(Coated; Blue)	BVX-LC04T-NS	IIb
	BVX-LB02T-NS	IIb
	BVX-LS05T-NS	IIb
	BVX-LJ07T-NS	IIb
	BVX-LH08T-NS	IIb
	BVX-LH01T-NS	IIb
	BVX-LN03T-NS	IIb
Suction Coagulator		
	SCH08	IIb
	SCH10	IIb
	SCH12	IIb
	SCF08	IIb
	SCF10	IIb
	SCF12	IIb

Products included in the Product List to Certificate No: 41313069-02

Product category	Type/Model designation	Class
Class I sterile devices		
Lighted Orotracheal Intubation Stylets	SLOT	Is
	PDOT	Is
Handpiece Sheath	A910ST	Is
Eye Bubble	0002	Is
Sterile Hose Tube	786TS/ Model ARVT10424	Is
Vacuum Hose	SETWS/ Model ARVTWT424	Is
Sterile Tube and Adaptor	SERFS/ Model ARRF10210	Is
Sterile Hose and Adaptor	SEVL/ Model ARVTVIC05	Is
Sterile Adaptor and Tubing	SEPA/ Model PA1025	Is
Sterile Adaptor and Tubing	SEPAT/PA2010	Is

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
19 Sep 2023	MDD Extension Confirmation Letter - Bovie Medical - 01	