

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Bovie Medical Corporation

Main Site: 5115 Ulmerton Road, Clearwater, FL 33760, USA

Product Category:

- Electrosurgery equipment including accessories (Class IIb)
- Cauteries (Class IIb)
- Surgical lights, disposable nerve locators, ophthalmology burrs and power handles (Class IIa)

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41312698-01

Initial Certification Date:

2 November 2003

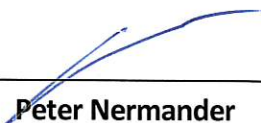
Certificate Valid from:

18 November 2018

Certificate Expiry Date:

17 November 2023




Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

5 November 2018

Signed Date

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medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.



Products included in the Certificate No: 41312698-01
 Issued to: **Bovie Medical Corporation**
 5115 Ulmerton Road
 Clearwater, FL 33760
 USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Surgical lights, disposable nerve locators, ophthalmology burrs and power handles					
Surgical Light					
	ST05	Ila	Yes		*
	ST10	Ila	Yes		*
	ST15	Ila	Yes		*
Nerve Locators					
	0003Y	Ila	Yes		*
Ophthalmic Burrs					
	0001	Ila	Yes		*
	0011	Ila	No		*
	0012	Ila	No		*
	AB01	Ila	Yes		*
	AB05	Ila	Yes		*
Ophthalmic Power handles					
	0010	Ila	No		*
Cauteries					
High Temperature Cauteries					
	AA01X	Ilb	Yes		*
	AA03X	Ilb	Yes		*
	AA05X	Ilb	Yes		*
	AA09	Ilb	Yes		*
	AA11	Ilb	Yes		*
	AA17	Ilb	Yes		*
	AA17X	Ilb	Yes		Dec 19, 2014
	AA21X	Ilb	Yes		*
	20-HM-3000	Ilb	Yes		June 5, 2014
High Temperature Snap Design Cauteries					
	AA01	Ilb	Yes		Dec 13, 2013
	AA03	Ilb	Yes		Dec 13, 2013
	AA05	Ilb	Yes		Dec 13, 2013
	AA17	Ilb	Yes		Dec 19, 2014
	AA21	Ilb	Yes		Dec 13, 2013
	0231	Ilb	Yes		June 5, 2014
	0233	Ilb	Yes		June 5, 2014
	0235	Ilb	Yes		June 5, 2014
	2231	Ilb	Yes		June 5, 2014
	20-HM-1000	Ilb	Yes		June 5, 2014
	20-HM-2000	Ilb	Yes		June 5, 2014

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	AA25	IIb	Yes		March 20, 2015
	AA27	IIb	Yes		March 20, 2015
	AA29	IIb	Yes		March 20, 2015
Ophthalmic Cauteries					
	AA00X	IIb	Yes		*
	AA02	IIb	Yes		*
	AA04X	IIb	Yes		*
	0230	IIb	Yes		June 5, 2014
	SOSCAA04	IIb	Yes		June 5, 2014
	SOSCAA90	IIb	Yes		June 5, 2014
Ophthalmic Snap Design Cauteries					
	AA00	IIb	Yes		Dec 13, 2013
	AA04	IIb	Yes		Dec 13, 2013
	AA90	IIb	Yes		March 20, 2015
Electrosurgery equipment including accessories					
Replaceable Tips					
	CH05	IIb	Yes		*
	H100	IIb	Yes		*
	H101	IIb	Yes		*
	H101-ADH	IIb	Yes		*
	H103	IIb	Yes		*
	H104	IIb	Yes		*
	H105	IIb	Yes		*
	H106	IIb	Yes		*
	H109	IIb	Yes		*
	H110	IIb	Yes		*
	H111	IIb	Yes		*
	H112	IIb	Yes		*
	H121	IIb	Yes		*
Replaceable Tip Kits					
	DEL0	IIb	No		*
	DEL1	IIb	No		*
	DEL2	IIb	No		*
	HIT0	IIb	No		*
	HIT1	IIb	No		*
Electrosurgery Equipment and Accessories: Generators					
		IIb	No		*
	A940	IIb	No		*
	DERM 941 A941	IIb	No		Jan 29, 2016
	DERM 942 A942	IIb	No		Jan 29, 2016
	Bantam/PRO A952	IIb	No		Jan 29, 2016
	A1210D	IIb	No		May 6, 2015

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Intertek Semko AB

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Registered in Sweden: No SE556024059901, Registered office: As address

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	A1210R	IIb	No		May 6, 2015
	A1250U-COV	IIb	No		July 25, 2016
	A1250U	IIb	No		*
	A1250S	IIb	No		Nov 20, 2015
	A2350	IIb	No		Dec 6, 2013
	A3350	IIb	No		Dec 6, 2013
	IDS-210	IIb	No		Dec 6, 2013
	IDS-310	IIb	No		Dec 6, 2013
	IDS-310T	IIb	No		March 20, 2015
	ASG-120	IIb	No		Dec 6, 2013
	J-Plasma Handpiece 1.8cm, with Blade BVX-018B	IIb	Yes		Dec 19, 2014
	J-Plasma Handpiece 1.8cm, with Needle BVX-018N	IIb	Yes		Dec 19, 2014
	J-Plasma Handpiece GS-018C	IIb	Yes		Dec 19, 2014
	J-Plasma Precise Open 44 mm, with Blade BVX-044-BPS	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 44 mm, with Blade BVX -044-NPS	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 44 mm, with Blade BVX-044-BPP	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 44 mm, with Blade BVX -044-NPP	IIb	Yes		Mar 13, 2017
	J-Plasma Handpiece 10cm, with Blade BVX-100B	IIb	Yes		Dec 19, 2014
	Bovie Ultimate Generator BVX-100H	IIb	No		Dec 19, 2014

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	J-Plasma Handpiece 10cm, with Needle BVX-100N	IIb	Yes		Dec 19, 2014
	J-Plasma Handpiece 15cm, with Blade BVX-150B	IIb	Yes		Nov 20, 2015
	J-Plasma Handpiece 15cm, with Needle BVX-150N	IIb	Yes		Nov 20, 2015
	J-Plasma Precise Open 150 mm, with Blade BVX -150-BPS	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 150 mm, with Blade BVX -150-NPS	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 150 mm, with Blade BVX -150-BPP	IIb	Yes		Mar 13, 2017
	J-Plasma Precise Open 150 mm, with Blade BVX -150-NPP	IIb	Yes		Mar 13, 2017
	Bovie Ultimate BVX-200H	IIb	No		Mar 13, 2017
	Bovie Ultimate BVX-200P	IIb	No		Mar 13, 2017
	J-Plasma Footswitch BVX-JPDFS	IIb	No		Mar 13, 2017
	J-Plasma Handpiece 27cm, with Blade BVX-270B	IIb	Yes		Dec 19, 2014
	J-Plasma Handpiece 27cm, with Needle BVX-270N	IIb	Yes		Dec 19, 2014
	J-Plasma Handpiece GS-270C	IIb	Yes		Dec 19, 2014

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	J-Plasma Handpiece 33cm, with Blade BVX-330B	IIb	Yes		Dec 19, 2014
	J-Plasma Precise 360 Laparoscopic Handpiece 33cm, with Blade BVX-330BR	IIb			Nov 20, 2015
	J-Plasma Handpiece 33cm, with Needle BVX-330N	IIb	Yes		Dec 19, 2014
	J-Plasma Precise 360 Laparoscopic Handpiece 33cm, with Needle BVX-330NR	IIb			Nov 20, 2015
	J-Plasma Handpiece 45cm, with Blade BVX-450B	IIb	Yes		Dec 19, 2014
	J-Plasma Precise 360 Laparoscopic Handpiece 45cm, with Blade BVX-450BR	IIb	Yes		Nov 20, 2015
	J-Plasma Handpiece 45cm, with Needle BVX-450N	IIb	Yes		Dec 19, 2014
	J-Plasma Precise 360 Laparoscopic Handpiece 45cm, with Needle BVX-450NR	IIb	Yes		Nov 20, 2015
	J-Plasma Precise Flexible, with Blade BVX-500BF	IIb	Yes		May 15, 2017
	DERM 102	IIb	No		Feb 15, 2018
	DERM 101	IIb	No		Feb 15, 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	EM010 High Frequency Electrosurgical Generator	IIB	No		May 16, 2018
Electrosurgical Generator Accessory					
	Bovie Ultimate Generator Helium Gas Regulator BV-HGS	IIB	No		July 1, 2016
Electrosurgery Equipment and Accessories: Capacitive Grounding Plate					
	A1452C	IIB	No		May 30, 2011
Electrosurgery Equipment and Accessories: Pencils					
	A801EU	IIB	No		*
	A901	IIB	No		*
	A902	IIB	No		Mar 28, 2014
	AR-9610H	IIB	Yes		*
	AR-9610SP	IIB	Yes		*
	ESP1	IIB	Yes		*
	ESP1H	IIB	Yes		*
	ESP1HN	IIB	Yes		
	ESP1HS	IIB	Yes		*
	ESP1N	IIB	Yes		*
	ESP6	IIB	Yes		*
	ESP6H	IIB	Yes		*
	ESP6HN	IIB	Yes		
	ESP6HS	IIB	Yes		*
	ESP6N	IIB	Yes		*
	ESP7	IIB	Yes		*
	ESP7H	IIB	Yes		*
	ESP7HN	IIB	Yes		*
	ESP7HS	IIB	Yes		*
	ESP7N	IIB	Yes		*
	ESPH	IIB	Yes		*
	ESPR	IIB	No		*
	ESPR2	IIB	No		May 30, 2011
	ESPR-EL	IIB	No		Sep 12, 2014
	ESPRS	IIB	Yes		*
	ESSP	IIB	Yes		*
	ESP1T	IIB	Yes		October 22, 2012
	ESP1TN	IIB	Yes		October 22, 2012
	ESP6T	IIB	Yes		October 22, 2012
	ESP6TN	IIB	Yes		October 22, 2012

Electrodes; Standard				
ES01	IIb	Yes	*	
ES02	IIb	Yes	*	
ES03	IIb	Yes	*	
ES04	IIb	Yes	*	
ES06	IIb	Yes	*	
ES07	IIb	Yes	*	
ES18	IIb	Yes	*	
ES20	IIb	Yes	*	
ES21	IIb	Yes	*	
ES37	IIb	Yes	*	
ES38	IIb	Yes	*	
ES39	IIb	Yes	*	
ES40	IIb	Yes	*	
ES50	IIb	Yes	*	
ES54	IIb	Yes		July 1, 2010
ES55	IIb	Yes		July 1, 2010
ES58	IIb	Yes		July 1, 2010
ES59	IIb	Yes		July 1, 2010
ES06-NS	IIb	No		June 11, 2012
ES07-NS	IIb	No		June 11, 2012
ES65-NS	IIb	No		June 11, 2012
ES67-NS	IIb	No		June 11, 2012
ES68-NS	IIb	No		June 11, 2012
ES70-NS	IIb	No		June 11, 2012
ES71	IIb	Yes		Dec 19, 2014
ES71-NS	IIb	No		Dec 19, 2014
809315	IIb	Yes		June 5, 2014
809316	IIb	Yes		Dec 19, 2014
809317	IIb	Yes		June 5, 2014
809318	IIb	Yes		June 5, 2014
809319	IIb	Yes		June 5, 2014
809335	IIb	Yes		June 5, 2014
809337	IIb	Yes		June 5, 2014
809338	IIb	Yes		June 5, 2014
809339	IIb	Yes		June 5, 2014
Electrodes; Loop				
ES08	IIb	Yes	*	
ES09	IIb	Yes	*	
ES10	IIb	Yes	*	
ES11	IIb	Yes	*	
ES12	IIb	Yes	*	
ES13	IIb	Yes	*	
ES14	IIb	Yes	*	
ES15	IIb	Yes	*	
ES16	IIb	Yes	*	
ES31	IIb	Yes	*	
ES41	IIb	Yes	*	

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ES42	IIb	Yes	*
ES43	IIb	Yes	*
ES44	IIb	Yes	*
ES45	IIb	Yes	*
ES46	IIb	Yes	*
ES47	IIb	Yes	*
ES49	IIb	Yes	*
ES51	IIb	Yes	*
ES52	IIb	Yes	*
ES53	IIb	Yes	*
ESLK	IIb	Yes	July 1, 2010
ES09-NS	IIb	No	June 11, 2012
ES13-NS	IIb	No	June 11, 2012
ES42-NS	IIb	No	June 11, 2012
ES53-NS	IIb	No	June 11, 2012
Tungsten Needle Electrodes			
A834	IIb	Yes	July 1, 2010
A834T	IIb	Yes	July 1, 2010
ES60	IIb	Yes	*
ES61	IIb	Yes	*
ES61HS	IIb	Yes	July 1, 2010
ES62	IIb	Yes	*
ES63	IIb	Yes	*
ES61-NS	IIb	No	June 11, 2012
ES63-NS	IIb	No	June 11, 2012
Tungsten Needle Electrodes Reusable			
ES60R	IIb	No	July 1, 2010
ES62R	IIb	No	July 1, 2010
Tungsten Loop Electrodes			
ES22	IIb	Yes	*
ES23	IIb	Yes	*
ES24	IIb	Yes	*
ES25	IIb	Yes	*
ES26	IIb	Yes	*
ES14-NS	IIb	No	June 11, 2012
ES15-NS	IIb	No	June 11, 2012
ES16-NS	IIb	No	June 11, 2012
Tungsten Loop Electrodes Reusable			
ES22R	IIb	No	*
ES23R	IIb	No	*
ES24R	IIb	No	*
ES25R	IIb	No	*
ES26R	IIb	No	*
Tungsten Loop Electrodes (.008 wire)			
ES22-8	IIb	No	*
ES23-8	IIb	No	*
ES24-8	IIb	No	*
ES25-8	IIb	No	*

	ES26-8	IIb	No	*
Reusable Electrodes				
	A811	IIb	No	*
	A830	IIb	No	*
	A831	IIb	No	*
	A832	IIb	No	*
	A833	IIb	No	*
	A834	IIb	No	*
	A836	IIb	No	*
	ES01R	IIb	No	*
	ES02R	IIb	No	*
	ES03R	IIb	No	*
	ES04R	IIb	No	*
	ES06R	IIb	No	*
	ES07R	IIb	No	*
	ES08R	IIb	No	*
	ES09R	IIb	No	*
	ES10R	IIb	No	*
	ES11R	IIb	No	*
	ES12R	IIb	No	*
	ES13R	IIb	No	*
	ES14R	IIb	No	*
	ES15R	IIb	No	*
	ES16R	IIb	No	*
	ES18R	IIb	No	*
	ES20R	IIb	No	*
	ES21R	IIb	No	*
	ES31R	IIb	No	*
	ES41R	IIb	No	*
	ES42R	IIb	No	*
	ES43R	IIb	No	*
	ES44R	IIb	No	*
	ES45R	IIb	No	*
	ES46R	IIb	No	*
	ES47R	IIb	No	*
	ES49R	IIb	No	*
	ES50R	IIb	No	*
	ES51R	IIb	No	*
	ES52R	IIb	No	*
	ES53R	IIb	No	*
	ES54R	IIb	No	July 1, 2010
	ES55R	IIb	No	July 1, 2010
	ES58R	IIb	No	July 1, 2010
	ES60R	IIb	No	*
	ES61R	IIb	No	*
	ES62R	IIb	No	*

Coated Electrodes				
BVX01T	IIb	Yes	Sept 8, 2010	
BVX02T	IIb	Yes	Sept 8, 2010	
BVX03T	IIb	Yes	Sept 8, 2010	
BVX04T	IIb	Yes	Sept 8, 2010	
BVX06T	IIb	Yes	Sept 8, 2010	
BVX07T	IIb	Yes	Sept 8, 2010	
BVX18T	IIb	Yes	Sept 8, 2010	
BVX20T	IIb	Yes	Sept 8, 2010	
BVX21T	IIb	Yes	Sept 8, 2010	
BVX37T	IIb	Yes	Sept 8, 2010	
BVX38T	IIb	Yes	Sept 8, 2010	
BVX39T	IIb	Yes	Sept 8, 2010	
BVX40T	IIb	Yes	Sept 8, 2010	
BVX50T	IIb	Yes	Sept 8, 2010	
BVX54T	IIb	Yes	Sept 8, 2010	
BVX55T	IIb	Yes	Sept 8, 2010	
BVX56T	IIb	Yes	Sept 8, 2010	
BVX57T	IIb	Yes	Sept 8, 2010	
ES01T	IIb	Yes	July 1, 2010	
ES02T	IIb	Yes	July 1, 2010	
ES03T	IIb	Yes	July 1, 2010	
ES04T	IIb	Yes	July 1, 2010	
ES06T	IIb	Yes	July 1, 2010	
ES07T	IIb	Yes	July 1, 2010	
ES0012AEU	IIb	Yes	Dec 19, 2014	
ES0013EU	IIb	Yes	Dec 19, 2014	
ES0014EU	IIb	Yes	Dec 19, 2014	
ES0016EU	IIb	Yes	Dec 19, 2014	
ES18T	IIb	Yes	July 1, 2010	
ES20T	IIb	Yes	July 1, 2010	
ES21T	IIb	Yes	July 1, 2010	
ES37T	IIb	Yes	July 1, 2010	
ES38T	IIb	Yes	July 1, 2010	
ES39T	IIb	Yes	July 1, 2010	
ES40T	IIb	Yes	July 1, 2010	
ES50T	IIb	Yes	July 1, 2010	
ES54T	IIb	Yes	July 1, 2010	
ES55T	IIb	Yes	July 1, 2010	
ES56T	IIb	Yes	July 1, 2010	
ES57T	IIb	Yes	July 1, 2010	
ES58T	IIb	Yes	July 1, 2010	
ES59T	IIb	Yes	July 1, 2010	
ES65T	IIb	Yes	Dec 5, 2014	
ES66T	IIb	Yes	Dec 5, 2014	
ES0012AMEU	IIb	Yes	Dec 5, 2014	
ES0014AMEU	IIb	Yes	Dec 5, 2014	

Electrodes (Coated; Black; Non Sterile)				
ES01BT-NS	IIb	No	Aug 7, 2013	
ES02BT-NS	IIb	No	Aug 7, 2013	
ES03BT-NS	IIb	No	Aug 7, 2013	
ES04BT-NS	IIb	No	Aug 7, 2013	
ES06BT-NS	IIb	No	Aug 7, 2013	
ES07BT-NS	IIb	No	Aug 7, 2013	
ES18BT-NS	IIb	No	Aug 7, 2013	
ES20BT-NS	IIb	No	Aug 7, 2013	
ES21BT-NS	IIb	No	Aug 7, 2013	
ES50BT-NS	IIb	No	Aug 7, 2013	
ES55BT-NS	IIb	No	Aug 7, 2013	
ES56BT-NS	IIb	No	Aug 7, 2013	
ES58BT-NS	IIb	No	Aug 7, 2013	
ES64BT-NS	IIb	No	Aug 7, 2013	
ES66BT-NS	IIb	No	Aug 7, 2013	
ES67BT-NS	IIb	No	Aug 7, 2013	
ES68BT-NS	IIb	No	Aug 7, 2013	
ES69BT-NS	IIb	No	Aug 7, 2013	
ES70BT-NS	IIb	No	Aug 7, 2013	
Electrodes (Coated; Blue; Non-Sterile)				
ES01T-NS	IIb	No	Sept 8, 2010	
ES02T-NS	IIb	No	Sept 8, 2010	
ES03T-NS	IIb	No	Sept 8, 2010	
ES04T-NS	IIb	No	Sept 8, 2010	
ES06T-NS	IIb	No	Sept 8, 2010	
ES07T-NS	IIb	No	Sept 8, 2010	
ES18T-NS	IIb	No	Sept 8, 2010	
ES20T-NS	IIb	No	Sept 8, 2010	
ES21T-NS	IIb	No	Sept 8, 2010	
ES37T-NS	IIb	No	Sept 8, 2010	
ES38T-NS	IIb	No	Sept 8, 2010	
ES39T-NS	IIb	No	Sept 8, 2010	
ES40T-NS	IIb	No	Sept 8, 2010	
ES50T-NS	IIb	No	Sept 8, 2010	
ES54T-NS	IIb	No	Sept 8, 2010	
ES55T-NS	IIb	No	Sept 8, 2010	
ES56T-NS	IIb	No	Sept 8, 2010	
ES57T-NS	IIb	No	Sept 8, 2010	
ES58T-NS	IIb	No	Sept 8, 2010	
ES59T-NS	IIb	No	Sept 8, 2010	
ES64T-NS	IIb	No	June 11, 2012	
ES65T-NS	IIb	No	June 11, 2012	
ES66T-NS	IIb	No	June 11, 2012	
ES67T-NS	IIb	No	June 11, 2012	
ES68T-NS	IIb	No	June 11, 2012	
ES69T-NS	IIb	No	June 11, 2012	
ES70T-NS	IIb	No	June 11, 2012	

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Dermal Tip Electrodes				
A804	IIb	No	*	
A805	IIb	Yes	*	
A806	IIb	No	*	
A806DE	IIb	No	Apr 25, 2014	
A807	IIb	Yes	*	
A807DE	IIb	Yes	Apr 25, 2014	
Electrode Sharp Tip Non-Sterile 100/Box H10012	IIb	No	June 30, 2017	
Electrode Sharp Tip Sterile 50/Box H10008	IIb	Yes	June 30, 2017	
Electrode Blunt Angled Blade Non- Sterile 100/Box H10112	IIb	No	June 30, 2017	
Electrode Blunt Angled Blade Sterile 50/Box H10208	IIb	Yes	June 30, 2017	
Arthroscopic Electrodes				
AR00	IIb	Yes	*	
AR01	IIb	Yes	*	
AR02	IIb	Yes	*	
AR03	IIb	Yes	*	
AR00-NS	IIb	No	June 11, 2012	
AR01-NS	IIb	No	June 11, 2012	
AR02-NS	IIb	No	June 11, 2012	
BA3390A 3.3mm Disposable Bipolar Ablator 90°, Aspirating	IIb	Yes	Jan 29, 2016	
C3390A 3.3mm UltrAblator Bipolar 90°, Aspirating	IIb	Yes	Apr 26, 2017	
7201 3.3mm Disposable Bipolar Ablator – Private Label 90°, Aspirating	IIb	Yes	Mar 13, 2017	
BA3390NA 3.3mm Disposable Bipolar Ablator 90°, Non-Aspirating	IIb	Yes	Jan 29, 2016	

C3390NA 3.3mm UltraAblator Bipolar 90°, Non-Aspirating	IIb	Yes	Apr 26, 2017
7202 3.3mm Disposable Bipolar Ablator – Private Label 90°, Non-Aspirating	IIb	Yes	Mar 13, 2017
BA3350A 3.3mm Disposable Bipolar Ablator 50°, Aspirating	IIb	Yes	Jan 29, 2016
C3350A 3.3mm UltraAblator Bipolar 50°, Aspirating	IIb	Yes	Apr 26, 2017
7203 3.3mm Disposable Bipolar Ablator – Private Label 50°, Aspirating	IIb	Yes	Mar 13, 2017
BA3350NA 3.3mm Disposable Bipolar Ablator 50°, Non-Aspirating	IIb	Yes	Jan 29, 2016
C3350NA 3.3mm UltraAblator Bipolar 50°, Non-Aspirating	IIb	Yes	Apr 26, 2017
7204 3.3mm Disposable Bipolar Ablator – Private Label 50°, Non-Aspirating	IIb	Yes	Mar 13, 2017
BA2455NA 2.4mm Disposable Bipolar Ablator 55°, Non-Aspirating	IIb	Yes	Jan 29, 2016
C2455NA 2.4mm UltraAblator Bipolar 55°, Non-Aspirating	IIb	Yes	Apr 26, 2017
7205 2.4mm Disposable Bipolar Ablator – Private Label 55°, Non-Aspirating	IIb	Yes	Mar 13, 2017

	BA1860NA 1.8mm Disposable Bipolar Ablator 60°, Non-Aspirating	IIb	Yes	Jan 29, 2016
	C1860NA 1.8mm UltrAblator Bipolar 60°, Non-Aspirating	IIb	Yes	Apr 26, 2017
	7206 1.8mm Disposable Bipolar Ablator – Private Label 60°, Non-Aspirating	IIb	Yes	Mar 13, 2017
Forceps				
	A820	IIb	Yes	*
	A821	IIb	Yes	*
	A822	IIb	Yes	*
	A823	IIb	Yes	*
	A824	IIb	Yes	*
	A825	IIb	Yes	*
	A826	IIb	Yes	*
	A827BP	IIb	No	Apr 25, 2014
	A827F	IIb	No	Apr 25, 2014
	A827V	IIb	Yes	July 1, 2010
	A840	IIb	Yes	*
	A841	IIb	Yes	*
	A842	IIb	Yes	*
	A843	IIb	Yes	*
	A844	IIb	Yes	*
	A845	IIb	Yes	*
Electrode Adapter				
	A905B (0.8mm)	IIb	No	*
	A905B-1 (1.25mm)	IIb	No	*
	A905EL (1.5mm)	IIb	No	*
Remote Switch				
	RHSW	IIb	Yes	*
	RHSW-L	IIb	Yes	*
Footswitch				
	A1203	IIb	No	*
	A1203W	IIb	No	*
	A1253	IIb	No	*
	A1253-H	IIb	No	*
	AR-9600FB	IIb	No	*
	AR-9600FM	IIb	No	*
	BV-1253B	IIb	No	*
	BV-1253BGI	IIb	No	*
	BV-1254B	IIb	No	*

	Bovie Ultimate Generator Plasma Footswitch BVX-JPHFS	IIb	No	July 1, 2016
	A803	IIb	No	Sept 20, 2018
Bendable Needle Electrodes Reusable				
	ELA9B	IIb	Yes	Feb 6, 2012
	ELA1B	IIb	Yes	Feb 6, 2012
	ELA2B	IIb	Yes	Feb 6, 2012
	ELA3B	IIb	Yes	Feb 6, 2012
	ELF1B	IIb	Yes	Feb 6, 2012
	ELA8B	IIb	Yes	Feb 6, 2012
Bendable Round Loop Electrodes Reusable				
	ELB1B	IIb	Yes	Feb 6, 2012
	ELB2B	IIb	Yes	Feb 6, 2012
	ELB3B	IIb	Yes	Feb 6, 2012
	ELB4B	IIb	Yes	Feb 6, 2012
	ELB5B	IIb	Yes	Feb 6, 2012
	ELB6B	IIb	Yes	Feb 6, 2012
Bendable Diamond Loop Electrodes Reusable				
	ELC1B	IIb	Yes	Feb 6, 2012
	ELC3B	IIb	Yes	Feb 6, 2012
	ELC17B	IIb	Yes	Feb 6, 2012
	ELC6B	IIb	Yes	Feb 6, 2012
	ELC18B	IIb	Yes	Feb 6, 2012
Bendable Triangle Loop Electrodes Reusable				
	ELC7B	IIb	Yes	Feb 6, 2012
	ELC8B	IIb	Yes	Feb 6, 2012
Bendable Ball Electrodes Reusable				
	ELD3B	IIb	Yes	Feb 6, 2012
	ELD8B	IIb	Yes	Feb 6, 2012
Bendable Scalpel Electrodes				
	ELE1B	IIb	Yes	Feb 6, 2012
	ELE3B	IIb	Yes	Feb 6, 2012
Insulated Needle Electrodes Exposed Tip Reusable				
	ELD6B	IIb	Yes	Feb 6, 2012
	ELD6C	IIb	Yes	Feb 6, 2012
Insulated Sclerotherapy Needles				
	ELD41	IIb	Yes	Feb 6, 2012
	ELD42	IIb	Yes	Feb 6, 2012
Disposable electrodes				
	ELA2D	IIb	Yes	Feb 6, 2012
	ELA8D	IIb	Yes	Feb 6, 2012
	ELB1D	IIb	Yes	Feb 6, 2012
	ELB2D	IIb	Yes	Feb 6, 2012
	ELD8D	IIb	Yes	Feb 6, 2012
	ELE3D	IIb	Yes	Feb 6, 2012
	ELF1D	IIb	Yes	Feb 6, 2012
	ELC3D	IIb	Yes	Feb 6, 2012

Product List for Certificate No: 41312698-01
Date: November 18, 2018
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Electrodes Assortment Pack				
	ELPK40	IIb	Yes	Feb 6, 2012
Laparoscopic Instrument				
	BVX-AG3301	IIb	Yes	Feb 6, 2012
	BVX-AG3301-2.5	IIb	Yes	Feb 6, 2012
	BVX-AG3301R	IIb	Yes	Feb 6, 2012
	BVX-AG3301R-2.5	IIb	Yes	Feb 6, 2012
	BVX-AT3301	IIb	Yes	Feb 6, 2012
	BVX-AT3301R	IIb	Yes	Feb 6, 2012
	BVX-BB3301	IIb	Yes	Feb 6, 2012
	BVX-BB3301R	IIb	Yes	Feb 6, 2012
	BVX-BB4501	IIb	Yes	Feb 6, 2012
	BVX-BB4501R	IIb	Yes	Feb 6, 2012
	BVX-BB3301W	IIb	Yes	Feb 6, 2012
	BVX-BB3301WR	IIb	Yes	Feb 6, 2012
	BVX-BB4501W	IIb	Yes	Feb 6, 2012
	BVX-BB4501WR	IIb	Yes	Feb 6, 2012
	BVX-BD3301	IIb	Yes	Feb 6, 2012
	BVX-BD3301R	IIb	Yes	Feb 6, 2012
	BVX-BF3301	IIb	Yes	Feb 6, 2012
	BVX-BF3301R	IIb	Yes	Feb 6, 2012
	BVX-BF3302	IIb	Yes	Feb 6, 2012
	BVX-BF3302R	IIb	Yes	Feb 6, 2012
	BVX-CD3301	IIb	Yes	Feb 6, 2012
	BVX-CD3301R	IIb	Yes	Feb 6, 2012
	BVX-CF3301	IIb	Yes	Feb 6, 2012
	BVX-CF3301R	IIb	Yes	Feb 6, 2012
	BVX-CS3301	IIb	Yes	Feb 6, 2012
	BVX-CS4501	IIb	Yes	Feb 6, 2012
	BVX-DB3301	IIb	Yes	Feb 6, 2012
	BVX-DB3301R	IIb	Yes	Feb 6, 2012
	BVX-DN3301	IIb	Yes	Feb 6, 2012
	BVX-DN3301R	IIb	Yes	Feb 6, 2012
	BVX-DT3301	IIb	Yes	Feb 6, 2012
	BVX-DT3301R	IIb	Yes	Feb 6, 2012
	BVX-EC3301	IIb	Yes	Feb 6, 2012
	BVX-EC3301R	IIb	Yes	Feb 6, 2012
	BVX-EC4501R	IIb	Yes	Feb 6, 2012
	BVX-FS3301	IIb	Yes	Feb 6, 2012
	BVX-FS3301R	IIb	Yes	Feb 6, 2012
	BVX-HS3301	IIb	Yes	Feb 6, 2012
	BVX-HS4501	IIb	Yes	Feb 6, 2012
	BVX-MF3301	IIb	Yes	Feb 6, 2012
	BVX-MF3301R	IIb	Yes	Feb 6, 2012
	BVX-ML3301	IIb	Yes	Feb 6, 2012
	BVX-ML3301-2.5	IIb	Yes	Feb 6, 2012
	BVX-ML3301R	IIb	Yes	Feb 6, 2012
	BVX-ML3301R-2.5	IIb	Yes	Feb 6, 2012

BVX-ML4501	IIb	Yes	Feb 6, 2012
BVX-RA3301	IIb	Yes	Feb 6, 2012
BVX-RA3301R	IIb	Yes	Feb 6, 2012
BVX-RG3301	IIb	Yes	Feb 6, 2012
BVX-RG3301R	IIb	Yes	Feb 6, 2012
BVX-SS3301	IIb	Yes	Feb 6, 2012
BVX-SS3301-2.5	IIb	Yes	Feb 6, 2012
BVX-SS3302	IIb	Yes	Feb 6, 2012
BVX-SS3303	IIb	Yes	Feb 6, 2012
BVX-SS3304	IIb	Yes	Feb 6, 2012
BVX-SS3305	IIb	Yes	Feb 6, 2012
BVX-SS3306	IIb	Yes	Feb 6, 2012
BVX-TG3301	IIb	Yes	Feb 6, 2012
BVX-TG3301R	IIb	Yes	Feb 6, 2012
BVX-VF3301	IIb	Yes	Feb 6, 2012
BVX-VF3301R	IIb	Yes	Feb 6, 2012
Laparoscopic Electrodes			
BVX-LL06-NS	IIb	No	June 20, 2013
BVX-LC04-NS	IIb	No	June 20, 2013
BVX-LB02-NS	IIb	No	June 20, 2013
BVX-LS05-NS	IIb	No	June 20, 2013
BVX-LJ07-NS	IIb	No	June 20, 2013
BVX-LH08-NS	IIb	No	June 20, 2013
BVX-LH01-NS	IIb	No	June 20, 2013
BVX-LN03-NS	IIb	No	June 20, 2013
LL06-NS	IIb	No	June 26, 2014
LC04-NS	IIb	No	June 26, 2014
LB02-NS	IIb	No	June 26, 2014
LS05-NS	IIb	No	June 26, 2014
LJ07-NS	IIb	No	June 26, 2014
LH08-NS	IIb	No	June 26, 2014
LH01-NS	IIb	No	June 26, 2014
LN03-NS	IIb	No	June 26, 2014
LL06	IIb	Yes	June 26, 2014
LC04	IIb	Yes	June 26, 2014
LB02	IIb	Yes	June 26, 2014
LS05	IIb	Yes	June 26, 2014
LJ07	IIb	Yes	June 26, 2014
LH08	IIb	Yes	June 26, 2014
LH01	IIb	Yes	June 26, 2014
LN03	IIb	Yes	June 26, 2014
BVX-LL06	IIb	Yes	June 26, 2014
BVX-LC04	IIb	Yes	June 26, 2014
BVX-LB02	IIb	Yes	June 26, 2014
BVX-LS05	IIb	Yes	June 26, 2014
BVX-LJ07	IIb	Yes	June 26, 2014
BVX-LH08	IIb	Yes	June 26, 2014
BVX-LH01	IIb	Yes	June 26, 2014

BVX-LN03	IIb	Yes	June 26, 2014
Laparoscopic Electrodes (Coated; Blue)			
BVX-LL06T-NS	IIb	No	June 20, 2013
BVX-LC04T-NS	IIb	No	June 20, 2013
BVX-LB02T-NS	IIb	No	June 20, 2013
BVX-LS05T-NS	IIb	No	June 20, 2013
BVX-LJ07T-NS	IIb	No	June 20, 2013
BVX-LH08T-NS	IIb	No	June 20, 2013
BVX-LH01T-NS	IIb	No	June 20, 2013
BVX-LN03T-NS	IIb	No	June 20, 2013
Laparoscopic Electrodes (Coated; Black;)			
LL06BT-NS	IIb	No	June 26, 2014
LC04BT-NS	IIb	No	June 26, 2014
LB02BT-NS	IIb	No	June 26, 2014
LS05BT-NS	IIb	No	June 26, 2014
LJ07BT-NS	IIb	No	June 26, 2014
LH08BT-NS	IIb	No	June 26, 2014
LH01BT-NS	IIb	No	June 26, 2014
LN03BT-NS	IIb	No	June 26, 2014
LL06BT	IIb	Yes	June 26, 2014
LC04BT	IIb	Yes	June 26, 2014
LB02BT	IIb	Yes	June 26, 2014
LS05BT	IIb	Yes	June 26, 2014
LJ07BT	IIb	Yes	June 26, 2014
LH08BT	IIb	Yes	June 26, 2014
LH01BT	IIb	Yes	June 26, 2014
LN03BT	IIb	Yes	June 26, 2014
BVX-LL06BT	IIb	Yes	June 26, 2014
BVX-LC04BT	IIb	Yes	June 26, 2014
BVX-LB02BT	IIb	Yes	June 26, 2014
BVX-LS05BT	IIb	Yes	June 26, 2014
BVX-LJ07BT	IIb	Yes	June 26, 2014
BVX-LH08BT	IIb	Yes	June 26, 2014
BVX-LH01BT	IIb	Yes	June 26, 2014
BVX-LN03BT	IIb	Yes	June 26, 2014
Suction Coagulator			
SCH08	IIb	Yes	Feb 6, 2012
SCH10	IIb	Yes	Feb 6, 2012
SCH12	IIb	Yes	Feb 6, 2012
SCF08	IIb	Yes	Feb 6, 2012
SCF10	IIb	Yes	Feb 6, 2012
SCF12	IIb	Yes	Feb 6, 2012

* Product added before July 1, 2010

Valid from: November 18, 2018
Date of Issue: November 5, 2018

Intertek Semko AB
Notified Body MDD



Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on
medical devices, with identification number 0413.

Certificate No: 41312698-01
Date: October 5, 2018
Handled by: Carolina Escobar
E-mail: medtechsweden@intertek.com

Bovie Medical Corporation

Att: Dr. Topaz Kirlaw
5115 Ulmerton Road
Clearwater, FL 33760
USA

Purpose	Five year extension assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Annual surveillance audits have been performed during the five year period. The most recent audit was performed November 14, 2017 in Florida by George Mason, Luis Lopes. Technical files were reviewed at Intertek's office by Maria Eklycke and Lian Zhang (Class IIb, MD1104, Electrosurgery Generators, Electrosurgical electrodes, Electrosurgery Generators Accessory, completed 2017-10-13) and Sofia Blad (Class IIa MD1104, Ophthalmic Burrs, completed 2018-03-07). All non-conformities from the activities have been closed. The five year extension assessment was performed at Intertek's office.
Scope of assessment	- Electrosurgery equipment including accessories (Class IIb) - Cauteries (Class IIb) - Surgical lights, disposable nerve locators, ophthalmology burrs and power handles (Class IIa)
Issue date of certificate	18 November 2018
Conclusions/Decisions	The scope has been slightly amended to join some product categories. Referring to the above, a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II, has been extended. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Annual follow-up assessments are going to be performed.
Appeals	Any appeal shall be submitted to the manager of Medical Regulatory Services, Intertek Semko AB, Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD


Peter Nermander
Certification Authority MDD

Bovie Medical Corporation
5115 Ulmerton Road
Clearwater,
Florida 33760

19 September 2023

MDD Extension Confirmation Letter - Bovie Medical – 01

**Reference: 41312698-01 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	Ila
	ST10	Ila
	ST15	Ila
Nerve Locators	0003Y	Ila
Ophthalmic Burrs	0001	Ila
	0011	Ila
	0012	Ila
	AB01	Ila
	AB05	Ila
Ophthalmic Power Handle	0010	Ila
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	IIb
	A942	
	Bantam/PRO	IIb
	A952	
	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 (Coated; Blue)	BVX-LL06T-NS	IIb
	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	

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	



EC Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 PA The Hague
The Netherlands

A handwritten signature in blue ink, appearing to read "David Ceretti", is written over a horizontal line.

6-19-2019

Date

David Ceretti
Regulatory Affairs Manager