

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

SNEDA PEDITE Accred. no. 1003 Certification of Management Systems ISO/IEC 17021-1

Peter Nermander Certification Authority MDD Intertek Semko AB, Kista, Sweden

5 November 2018

Signed Date

Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden Telephone +46 8 750 00 00 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.



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request





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	e locators, ophthalmo	logy burrs a	nd power	handles	
Surgical Light					
	ST05	lla	Yes		*
	ST10	lla	Yes		*
	ST15	lla	Yes		*
Nerve Locators					
	0003Y	lla	Yes		*
Ophthalmic Burrs					
	0001	lla	Yes		*
	0011	lla	No		*
	0012	lla	No		*
	AB01	lla	Yes		*
	AB05	lla	Yes		*
Ophthalmic Power handles					
·	0010	lla	No		*
Cauteries					
High Temperature Cauteries					
	AA01X	llb	Yes		*
	AA03X	llb	Yes		*
	AA05X	llb	Yes		*
	AA09	llb	Yes		*
	AA11	llb	Yes		*
	AA17	llb	Yes		*
	AA17X	llb	Yes		Dec 19, 2014
	AA21X	llb	Yes		*
	20-HM-3000	llb	Yes		June 5, 2014
High Temperature Snap Design	Cauteries				
	AA01	llb	Yes		Dec 13, 2013
	AA03	llb	Yes		Dec 13, 2013
	AA05	llb	Yes		Dec 13, 2013
	AA17	llb	Yes		Dec 19, 2014
	AA21	llb	Yes		Dec 13, 2013
	0231	llb	Yes		June 5, 2014
	0233	llb	Yes		June 5, 2014
	0235	llb	Yes		June 5, 2014
	2231	llb	Yes		June 5, 2014
	20-HM-1000	llb	Yes		June 5, 2014
	20-HM-2000	llb	Yes		June 5, 2014

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AA25 Ib Yes March 20, 201 AA27 IIb Yes March 20, 201 AA29 IIb Yes March 20, 201 Ophthalmic Cauteries * * * AA02 IIb Yes * AA02 IIb Yes * AA02 IIb Yes * Q230 IIb Yes June 5, 2014 SOSCAA04 IIb Yes June 5, 2014 SOSCAA04 IIb Yes June 5, 2014 Ophthalmic Snap Design Cauteries * June 5, 2014 Ophthalmic Snap Design Cauteries * March 20, 201 Electrosurgery equipment including accessories * * Replaceable Tips * * CH05 IIb Yes * H100 IIb Yes * H101-ADH IIb Yes * H103 IIb Yes * H104 IIb Yes	Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
AA29 IIb Yes March 20, 201 Ophthalmic Cauteries AA00X IIb Yes * AA02 IIb Yes * AA02 IIb Yes * AA04X IIb Yes * 0230 IIb Yes June 5, 2014 SOSCAA04 IIb Yes June 5, 2014 Ophthalmic Snap Design Cauteries June 5, 2014 Ophthalmic Snap Design Cauteries March 20, 201 Electrosurgery equipment including accessories * Replaceable Tips * * H100 IIb Yes * H101 IIb Yes * H102 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H104 IIb Yes * H104 IIb Yes		AA25	llb	Yes	manualory)	March 20, 2015
AA29 IIb Yes March 20, 201 Ophthalmic Cauteries AA00X IIb Yes * AA02 IIb Yes * AA02 IIb Yes * AA04X IIb Yes * Q230 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 AA90 IIb Yes March 20, 201 Betactable Tage * Placeable Tips CH05 IIb Yes * * H100 IIb Yes * * * H101 IIb Yes *		AA27	llb	Yes		March 20, 2015
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 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories * * Replaceable Tips CH05 IIb Yes * * H100 IIb Yes * * * H101-ADH IIb Yes * * H103 IIb Yes * * H104 IIb Yes * * H106 IIb Yes * * <td< td=""><td></td><td>AA29</td><td>llb</td><td>Yes</td><td></td><td>March 20, 2015</td></td<>		AA29	llb	Yes		March 20, 2015
AA002 IID 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	Ophthalmic Cauteries					
AA04X IIb Yes * 0230 IIb Yes June 5, 2014 SOSCAA04 IIb Yes June 5, 2014 SOSCAA00 IIb Yes June 5, 2014 Ophthalmic Snap Design Cauteries A000 IIb Yes Dec 13, 2013 AA04 IIb Yes Dec 13, 2013 AA04 IIb Yes March 20, 201 Electrosurgery equipment including accessories # March 20, 201 Electrosurgery equipment including accessories * * # # March 20, 201 Electrosurgery equipment including accessories * * * #		AA00X	llb	Yes		*
AA04A IID Yes June 5, 2014 Q230 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 Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories Replaceable Tips * * * * H100 IIb Yes * * * * H101 IIb Yes * * * * H103 IIb Yes * * *		AA02	llb	Yes		*
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 AA04 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories Replaceable Tips * * * Replaceable Tips CH05 IIb Yes * * H100 IIb Yes * * * H101 IIb Yes * * H103 IIb Yes * * H106 IIb Yes * * H108 IIb Yes * * H101 IIb Yes		AA04X	llb	Yes		*
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 Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories Replaceable Tips CH05 IIb Yes * H100 IIb Yes * H101 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H106 IIb Yes * H110 IIb Yes * H110 IIb Yes * H110 IIb Yes * H111 IIb Yes * H111 IIb Yes * <t< td=""><td></td><td>0230</td><td>llb</td><td>Yes</td><td></td><td>June 5, 2014</td></t<>		0230	llb	Yes		June 5, 2014
Ophthalmic Snap Design Cauteries AA00 Ilb Yes Dec 13, 2013 AA90 Ilb Yes Dec 13, 2013 AA90 Ilb Yes March 20, 201 Electrosurgery equipment including accessories Replaceable Tips * * * H100 Ilb Yes * * H101 Ilb Yes * H101 Ilb Yes * H101 Ilb Yes * H103 Ilb Yes * H104 Ilb Yes * H105 Ilb Yes * H106 Ilb Yes * H108 Ilb Yes * H110 Ilb Yes * H110 Ilb Yes * H111 Ilb Yes * H111 Ilb Yes * H111 Ilb Yes * DEL0 Ilb		SOSCAA04	llb	Yes		June 5, 2014
AA00 IIb Yes Dec 13, 2013 AA04 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories * * Replaceable Tips CH05 IIb Yes * H100 IIb Yes * * H101 IIb Yes * * H101 IIb Yes * * H101 IIb Yes * * H104 IIb Yes * * H105 IIb Yes * * H106 IIb Yes * * H110 IIb Yes * * H110 IIb Yes * * H111 IIb Yes * * H111 IIb No * *		SOSCAA90	llb	Yes		June 5, 2014
AA00 IIb Yes Dec 13, 2013 AA04 IIb Yes Dec 13, 2013 AA90 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories * * Replaceable Tips CH05 IIb Yes * H100 IIb Yes * * H101 IIb Yes * * H101 IIb Yes * * H101 IIb Yes * * H104 IIb Yes * * H105 IIb Yes * * H106 IIb Yes * * H110 IIb Yes * * H110 IIb Yes * * H111 IIb Yes * * H111 IIb No * *	Ophthalmic Snap Design Cauteri	es				
AA04 IIb Yes Dec 13, 2013 AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories March 20, 201 Replaceable Tips * H100 IIb Yes * H100 IIb Yes * H101 IIb Yes * H101 IIb Yes * H101 IIb Yes * H101 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H106 IIb Yes * H108 IIb Yes * H110 IIb Yes * H111 IIb Yes * H112 IIb Yes * DEL0 IIb No * DEL1 IIb No			llb	Yes		Dec 13, 2013
AA90 IIb Yes March 20, 201 Electrosurgery equipment including accessories Replaceable Tips * Replaceable Tips * * H100 IIb Yes * H100 IIb Yes * H101 IIb Yes * H101 IIb Yes * H101 IIb Yes * H101 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H107 IIb Yes * H110 IIb Yes * H111 IIb Yes * H112 IIb Yes * DEL0 IIb No * DEL1 IIb No * DEL2 IIb No		AA04	llb			Dec 13, 2013
Electrosurgery equipment including accessories Replaceable Tips H100 IIb Yes * H100 IIb Yes * H101 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H109 IIb Yes * H111 IIb Yes * H112 IIb Yes * H112 IIb Yes * H111 IIb No * DEL0 IIb No * DEL2 IIb No			llb	Yes		March 20, 2015
CH05 IIb Yes * H100 IIb Yes * H100 IIb Yes * H101 IIb Yes * H101-ADH IIb Yes * H103 IIb Yes * H103 IIb Yes * H104 IIb Yes * H106 IIb Yes * H106 IIb Yes * H109 IIb Yes * H110 IIb Yes * H111 IIb Yes * H111 IIb Yes * H111 IIb Yes * H111 IIb Yes * DEL0 IIb No * DEL1 IIb No * DEL2 IIb No * HIT0 IIb No *		ng accessories				·
H100 Hb Yes * H101 IIb Yes * H101 IIb Yes * H101 IIb Yes * H103 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H106 IIb Yes * H101 IIb Yes * H110 IIb Yes * H111 IIb Yes * H112 IIb Yes * H111 IIb Yes * H121 IIb No * DEL0 IIb No * DEL1 IIb No * HIT0 IIb No * HIT1 IIb No *	Replaceable Tips	CHOE	116	Va-		*
H100 H0 Hes H101-ADH IIb Yes * H101-ADH IIb Yes * H103 IIb Yes * H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 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 * DEL2 IIb No * HIT0 IIb No * HIT1 IIb No * Electrosurgery Equipment and Accessories: Generators *						
H101 Hb Yes * H103 Hb Yes * H103 Hb Yes * H104 Hb Yes * H105 Hb Yes * H106 Hb Yes * H106 Hb Yes * H109 Hb Yes * H110 Hb Yes * H110 Hb Yes * H111 Hb Yes * H112 Hb Yes * H112 Hb Yes * H121 Hb Yes * Replaceable Tip Kits * * * DEL0 Hb No * DEL2 Hb No * HT0 Hb No * HIT0 Hb No * HE A940 Hb No * <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>						
H101-ADH IID Yes H103 IIb Yes * H104 IIb Yes * H105 IIb Yes * H106 IIb Yes * H106 IIb Yes * H109 IIb Yes * H110 IIb Yes * H110 IIb Yes * H111 IIb Yes * H111 IIb Yes * H111 IIb Yes * H112 IIb Yes * H121 IIb Yes * DEL0 IIb No * DEL2 IIb No * HIT0 IIb No * HIT1 IIb No * Electrosurgery Equipment and Accessories: Generators * * DERM 941 IIb No \$ <						
H103 Hb Yes * H104 Hb Yes * H105 Hb Yes * H106 Hb Yes * H106 Hb Yes * H109 Hb Yes * H110 Hb Yes * H111 Hb Yes * H112 Hb Yes * H111 Hb Yes * H111 Hb Yes * H111 Hb Yes * H112 Hb Yes * H111 Hb No * DEL0 Hb No * DEL1 Hb No * HT0 Hb No * HT1 Hb No * Electrosurgery Equipment and Accessories: Generators * HT1 Hb No * DERM 941 Hb No Jan 29, 2016 A940 Hb No						
H104 Hb Tes H105 Ilb Yes * H106 Ilb Yes * H109 Ilb Yes * H109 Ilb Yes * H109 Ilb Yes * H110 Ilb Yes * H111 Ilb Yes * Replaceable Tip Kits DEL0 Ilb No * DEL2 Ilb No * * DEL2 Ilb No * * HIT0 Ilb No * * Electrosurgery Equipment and Accessories: Generators * * * DERM 941 Ilb No Jan 2						
H103 Hb Yes * H109 IIb Yes * H109 IIb Yes * H109 IIb Yes * H110 IIb Yes * H111 IIb Yes * H111 IIb Yes * H112 IIb Yes * H112 IIb Yes * Replaceable Tip Kits DEL0 IIb No * DEL1 IIb No * * DEL2 IIb No * * HIT0 IIb No * * Electrosurgery Equipment and Accessories: Generators IIb No * DERM 941 IIb No * * DERM 941 IIb No Jan 29, 2016 A941 DERM 942 IIb No Jan 29, 2016 A942 Bantam/PRO IIb No						
H100 H0 Yes H109 IIb Yes * H110 IIb Yes * H110 IIb Yes * H111 IIb Yes * H112 IIb Yes * H112 IIb Yes * H121 IIb Yes * Replaceable Tip Kits * * * DEL0 IIb No * DEL2 IIb No * HT0 IIb No * HIT1 IIb No * Electrosurgery Equipment and Accessories: Generators * * IIb No * * DERM 941 IIb No * DERM 942 IIb No Jan 29, 2016 A942 * * * DERM 942 IIb No Jan 29, 2016 A942 * *						
H109 Hb Yes H110 IIb Yes * H111 IIb Yes * H112 IIb Yes * H112 IIb Yes * H121 IIb Yes * Replaceable Tip Kits * * DEL0 IIb No * DEL1 IIb No * HIT0 IIb No * HIT1 IIb No * Electrosurgery Equipment and Accessories: Generators * * IIb No * * DERM 941 IIb No * DERM 941 IIb No Jan 29, 2016 A940 IIb No Jan 29, 2016 A941 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A942 <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td></t<>						
H110 Hb 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 * * Electrosurgery Equipment and Accessories: Generators * * * MIT1 IIb No * * Electrosurgery Equipment and Accessories: Generators * * * DERM 941 IIb No * * DERM 941 IIb No Jan 29, 2016 * A940 IIb No Jan 29, 2016 * DERM 942 IIb No Jan 29, 2016 * A942 * * * * * Bantam/PRO IIb						
H111 IID Tes 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 * * DERM 940 IIb No * DERM 941 IIb No Jan 29, 2016 A940 IIb No Jan 29, 2016 A941 Hb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A952 IIb No Jan 29, 2016						
H112 IID Tes 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 * * Electrosurgery Equipment and Accessories: Generators * * DERM 940 IIb No * DERM 941 IIb No # DERM 941 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 A952 IIb No Jan 29, 2016						
Initial Initial Replaceable Tip Kits DEL0 IIb No * DEL1 IIb No * DEL2 IIb No * HIT0 IIb No * Electrosurgery Equipment and Accessories: Generators IIb No * Electrosurgery Equipment and Accessories: Generators IIb No * DERM 941 IIb No * DERM 941 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 Bantam/PRO IIb No Jan 29, 2016 A952 IIb No Jan 29, 2016						
DEL0IIbNo*DEL1IIbNo*DEL2IIbNo*HIT0IIbNo*HIT1IIbNo*Electrosurgery Equipment and Accessories: Generators*Electrosurgery Equipment and Accessories: Generators*DERM 940IIbNo*DERM 941IIbNo3an 29, 2016A940DERM 942IIbNoJan 29, 2016A941DERM 942IIbNoJan 29, 2016A942DERM 942IIbNoJan 29, 2016A952Bantam/PROIIbNoJan 29, 2016		H121	llb	Yes		*
DEL1IIbNo*DEL2IIbNo*HIT0IIbNo*HIT1IIbNo*Electrosurgery Equipment and Accessories: GeneratorsIIbNo*A940IIbNo*DERM 941IIbNo*DERM 941IIbNoJan 29, 2016A942A942IIbNoJan 29, 2016A942IIbNoJan 29, 2016A942IIbNoJan 29, 2016A942IIbNoJan 29, 2016A952IIbNoJan 29, 2016	Replaceable Tip Kits					
DEL1IIDNODEL2IIbNo*HIT0IIbNo*HIT1IIbNo*Electrosurgery Equipment and Accessories: GeneratorsIIbNo*A940IIbNo*A940IIbNo*DERM 941IIbNoJan 29, 2016A941DERM 942IIbNoJan 29, 2016A942DERM 942IIbNoJan 29, 2016A942A942IIbNoJan 29, 2016A952A952An 29, 2016A952An 29, 2016						
DEL2IIDNOHIT0IIbNo*HIT1IIbNo*Electrosurgery Equipment and Accessories: GeneratorsIIbNo*A940IIbNo*DERM 941IIbNo4DERM 941IIbNoJan 29, 2016A941DERM 942IIbNoJan 29, 2016A942Bantam/PROIIbNoJan 29, 2016A952IIbNoJan 29, 2016						
HITOIIDNOHIT1IIbNo*Electrosurgery Equipment and Accessories: GeneratorsIIbNo*A940IIbNo*DERM 941IIbNoJan 29, 2016A941DERM 942IIbNoJan 29, 2016A942Bantam/PROIIbNoJan 29, 2016A952IIbNoJan 29, 2016						
Electrosurgery Equipment and Accessories: GeneratorsIIbNoA940IIbNoA940IIbNoDERM 941IIbNoA941IIbNoDERM 942IIbNoJan 29, 2016A942A942Bantam/PROIIbNoJan 29, 2016A952IIbNo						
IIb No * A940 IIb No * DERM 941 IIb No Jan 29, 2016 A941 IIb No Jan 29, 2016 DERM 942 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 Bantam/PRO IIb No Jan 29, 2016 A952 IIb No Jan 29, 2016			llb	No		*
A940 IIb No * DERM 941 IIb No Jan 29, 2016 A941 IIb No Jan 29, 2016 DERM 942 IIb No Jan 29, 2016 A942 IIb No Jan 29, 2016 Bantam/PRO IIb No Jan 29, 2016 A952 IIb No Jan 29, 2016	Electrosurgery Equipment and Ac	ccessories: Generators				
A940 IID NO DERM 941 IIb No Jan 29, 2016 A941 DERM 942 IIb No Jan 29, 2016 A942 Bantam/PRO IIb No Jan 29, 2016 A952 Bantam/PRO IIb No Jan 29, 2016						
A941 DERM 942 IIb No Jan 29, 2016 A942 Bantam/PRO IIb No Jan 29, 2016 A952						
DERM 942 IIb No Jan 29, 2016 A942 Bantam/PRO IIb No Jan 29, 2016 A952			llb	No		Jan 29, 2016
A942 Bantam/PRO IIb No Jan 29, 2016 A952						
Bantam/PRO IIb No Jan 29, 2016 A952			llb	No		Jan 29, 2016
A952						
			llb	No		Jan 29, 2016
		A1210D	llb	No		May 6, 2015

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

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



Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	J-Plasma Handpiece	llb	Yes	manualory)	Dec 19, 2014
	33cm, with Blade				
	BVX-330B				
	J-Plasma Precise 360	llb			Nov 20, 2015
	Laparoscopic				
	Handpiece				
	33cm, with Blade				
	BVX-330BR				_
	J-Plasma	llb	Yes		Dec 19, 2014
	Handpiece				
	33cm, with Needle				
	BVX-330N				NI 00 0015
	J-Plasma Precise 360	llb			Nov 20, 2015
	Laparoscopic				
	Handpiece				
	33cm, with Needle				
	BVX-330NR				
	J-Plasma	llb	Yes		Dec 19, 2014
	Handpiece				
	45cm, with Blade				
	BVX-450B				
	J-Plasma Precise 360	llb	Yes		Nov 20, 2015
	Laparoscopic				
	Handpiece				
	45cm, with Blade				
	BVX-450BR				
	J-Plasma Handpiece	llb	Yes		Dec 19, 2014
	45cm, with Needle BVX-450N				
	J-Plasma Precise	llb	Yes		Nov 20, 2015
	360				,
	Laparoscopic				
	Handpiece				
	45cm, with Needle				
	BVX-450NR				
	J-Plasma Precise	llb	Yes		May 15, 2017
	Flexible, with Blade				
	BVX-500BF				
	DERM 102	llb	No		Feb 15, 2018
	DERM 101	llb	No		Feb 15, 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	EM010 High Frequency	llb	No		May 16, 2018
	Electrosurgical Generator				
Electrosurgical Generator			N.L.		1 1 4 0040
	Bovie Ultimate Generator Helium Gas Regulator BV-HGS	llb	No		July 1, 2016
Electrosurgery Equipment	and Accessories: Capacitive	e Groundir	ng Plate		
Electrocargory Equipmont	A1452C	Ilb	No		May 30, 2011
Electrosurgery Equipment					
	A801EU	llb	No		*
	A901	llb	No		*
	A902	llb	No		Mar 28, 2014
	AR-9610H	llb	Yes		*
	AR-9610SP	llb	Yes		*
	ESP1	llb	Yes		*
	ESP1H	llb	Yes		*
	ESP1HN	llb	Yes		
	ESP1HS	llb	Yes		*
	ESP1N	llb	Yes		*
	ESP6	llb	Yes		*
	ESP6H	llb	Yes		*
	ESP6HN	llb	Yes		
	ESP6HS	llb	Yes		*
	ESP6N	llb	Yes		*
	ESP7	llb	Yes		*
	ESP7H	llb	Yes		*
	ESP7HN	llb	Yes		*
	ESP7HS	llb	Yes		*
	ESP7N	llb	Yes		*
	ESPH	llb	Yes		*
	ESPR	llb	No		*
	ESPR2	llb	No		May 30, 2011
	ESPR-EL	llb	No		Sep 12, 2014
	ESPRS	llb	Yes		*
	ESSP	llb	Yes		*
	ESP1T	llb	Yes	(October 22, 2012
	ESP1TN	llb	Yes	(October 22, 2012
	ESP6T	llb	Yes		October 22, 2012
	ESP6TN	llb	Yes	(October 22, 2012

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ES01	llb	Yes	*
ES02	llb	Yes	*
ES03	llb	Yes	*
ES04	llb	Yes	*
ES06	llb	Yes	*
ES07	llb	Yes	*
ES18	llb	Yes	*
ES20	llb	Yes	*
ES21	llb	Yes	*
ES37	llb	Yes	*
ES38	llb	Yes	*
ES39	llb	Yes	*
ES40	llb	Yes	*
ES50	llb	Yes	*
ES54	llb		July 1, 2010
ES55	llb		July 1, 2010
ES58	llb		July 1, 2010
			July 1, 2010
			June 11, 2012
			Dec 19, 2014
			Dec 19, 2014
			June 5, 2014
			Dec 19, 2014
			June 5, 2014
ES08	llb	Yes	*
			*
			*
			*
			*
			*
			*
ES15	IIb	Yes	*
	llh	Yes	*
ES16 ES31	llb llb	Yes Yes	*
	ES02 ES03 ES04 ES06 ES07 ES18 ES20 ES21 ES37 ES38 ES39 ES39 ES40 ES50 ES54	ES02 IIb ES03 IIb ES04 IIb ES06 IIb ES07 IIb ES18 IIb ES20 IIb ES21 IIb ES37 IIb ES38 IIb ES39 IIb ES50 IIb ES55 IIb ES55 IIb ES58 IIb ES67-NS IIb ES67-NS IIb ES71 Ib ES67-NS Ib ES71 Ib ES67-NS Ib ES71 Ib ES71 Ib B09315 Ib 809316 Ib 809317 Ib 809318 Ib 809335 Ib 809336 Ib 809337 Ib ES08 Ib 809338 Ib 809339 Ib B09338 Ib B09338 Ib <td>ES02 IIb Yes ES03 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 ES55 IIb Yes ES55 IIb Yes ES58 IIb Yes ES06-NS IIb No ES67-NS IIb No ES67-NS IIb No ES67-NS IIb No ES70-NS IIb No ES71-NS IIb No ES71-NS IIb No ES71-NS IIb No ES71-NS IIb Yes 809315</td>	ES02 IIb Yes ES03 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 ES55 IIb Yes ES55 IIb Yes ES58 IIb Yes ES06-NS IIb No ES67-NS IIb No ES67-NS IIb No ES67-NS IIb No ES70-NS IIb No ES71-NS IIb No ES71-NS IIb No ES71-NS IIb No ES71-NS IIb Yes 809315

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	ES42	llb	Yes	*
	ES43	llb	Yes	*
	ES44	llb	Yes	*
	ES45	llb	Yes	*
	ES46	llb	Yes	*
	ES47	llb	Yes	*
	ES49	llb	Yes	*
	ES51	llb	Yes	*
	ES52	llb	Yes	*
	ES53	llb	Yes	*
	ESLK	llb	Yes	July 1, 2010
	ES09-NS	llb	No	June 11, 2012
	ES13-NS	llb	No	June 11, 2012
	ES42-NS	llb	No	June 11, 2012
	ES53-NS	llb	No	June 11, 2012
Tungsten Needle Electrode		110		
	A834	llb	Yes	July 1, 2010
	A834T	llb	Yes	July 1, 2010
	ES60	llb	Yes	*
	ES61	Ilb	Yes	*
	ES61HS	Ilb	Yes	July 1, 2010
	ES62	Ilb	Yes	*
	ES63	Ilb	Yes	*
	ES61-NS	Ilb	No	June 11, 2012
	ES63-NS	IIb	No	June 11, 2012
Tungsten Needle Electrode			NO	Julie 11, 2012
	ES60R	llb	No	July 1, 2010
	ES62R	IIb	No	July 1, 2010
Tungsten Loop Electrodes	LOOZIN		NO	July 1, 2010
Tungsten Loop Liectiodes	ES22	llb	Yes	*
	ES23	llb	Yes	*
	ES24	llb		*
			Yes	*
	ES25	llb llb	Yes	*
	ES26		Yes	
	ES14-NS	llb	No	June 11, 2012
	ES15-NS	llb	No	June 11, 2012
T	ES16-NS	llb	No	June 11, 2012
Tungsten Loop Electrodes			N1.	*
	ES22R	llb	No	*
	ES23R	llb	No	*
	ES24R	llb	No	
	ES25R	llb	No	*
_	ES26R	llb	No	*
Tungsten Loop Electrodes	· · · · · · · · · · · · · · · · · · ·			
	ES22-8	llb	No	*
	ES23-8	llb	No	*
	ES24-8 ES25-8	llb llb	No No	*

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Total Quality. Assured.

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





Coated Electrodes	DVV04T	111-	Vaa	Cont 0, 0040
	BVX01T	llb	Yes	Sept 8, 2010
	BVX02T	llb	Yes	Sept 8, 2010
	BVX03T	llb	Yes	Sept 8, 2010
	BVX04T	llb	Yes	Sept 8, 2010
	BVX06T	llb	Yes	Sept 8, 2010
	BVX07T	llb	Yes	Sept 8, 2010
	BVX18T	llb	Yes	Sept 8, 2010
	BVX20T	llb	Yes	Sept 8, 2010
	BVX21T	llb	Yes	Sept 8, 2010
	BVX37T	llb	Yes	Sept 8, 2010
	BVX38T	llb	Yes	Sept 8, 2010
	BVX39T	llb	Yes	Sept 8, 2010
	BVX40T	llb	Yes	Sept 8, 2010
	BVX50T	llb	Yes	Sept 8, 2010
	BVX54T	llb	Yes	Sept 8, 2010
	BVX55T	llb	Yes	Sept 8, 2010
	BVX56T	llb	Yes	Sept 8, 2010
	BVX57T	llb	Yes	Sept 8, 2010
	ES01T	llb	Yes	July 1, 2010
	ES02T	llb	Yes	July 1, 2010
	ES03T	llb	Yes	July 1, 2010
	ES04T	llb	Yes	July 1, 2010
	ES06T	llb	Yes	July 1, 2010
	ES07T	llb	Yes	July 1, 2010
	ES0012AEU	llb	Yes	Dec 19, 2014
	ES0013EU	llb	Yes	Dec 19, 2014
	ES0016E0	llb	Yes	Dec 19, 2014
	ES0014E0	llb	Yes	Dec 19, 2014
	ES18T	llb	Yes	July 1, 2010
	ES20T	llb	Yes	July 1, 2010
	ES21T	llb	Yes	July 1, 2010
	ES37T	llb		
	ES38T	llb	Yes Yes	July 1, 2010 July 1, 2010
	ES39T			
		llb	Yes	July 1, 2010
	ES40T	llb	Yes	July 1, 2010
	ES50T	llb	Yes	July 1, 2010
	ES54T	llb	Yes	July 1, 2010
	ES55T	llb	Yes	July 1, 2010
	ES56T	llb	Yes	July 1, 2010
	ES57T	llb	Yes	July 1, 2010
	ES58T	llb	Yes	July 1, 2010
	ES59T	llb	Yes	July 1, 2010
	ES65T	llb	Yes	Dec 5, 2014
	ES66T	llb	Yes	Dec 5, 2014
	ES0012AMEU	llb	Yes	Dec 5, 2014
	ES0014AMEU	llb	Yes	Dec 5, 2014

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

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





C3390NA	llb	Yes	Apr 26, 2017
3.3mm UltrAblator			• • •
Bipolar 90°,			
Non-Aspirating			
7202	llb	Yes	Mar 13, 2017
3.3mm Disposable	no	163	Mai 10, 2017
-			
Bipolar Ablator –			
Private Label 90°,			
Non-Aspirating	llh	Vaa	lan 20, 2010
BA3350A	llb	Yes	Jan 29, 2016
3.3mm Disposable			
Bipolar Ablator 50°,			
Aspirating			
C3350A	llb	Yes	Apr 26, 2017
3.3mm UltrAblator			
Bipolar 50°,			
Aspirating			
7203	llb	Yes	Mar 13, 2017
3.3mm Disposable			, -
Bipolar Ablator –			
Private Label 50°,			
Aspirating			
BA3350NA	llb	Yes	Jan 29, 2016
	no	103	Jan 25, 2010
3.3mm Disposable			
Bipolar Ablator 50°,			
 Non-Aspirating			A 00. 0047
C3350NA	llb	Yes	Apr 26, 2017
3.3mm UltrAblator			
Bipolar 50°,			
Non-Aspirating			
7204	llb	Yes	Mar 13, 2017
3.3mm Disposable			
Bipolar Ablator –			
Private Label 50°,			
Non-Aspirating			
BA2455NA	llb	Yes	Jan 29, 2016
2.4mm Disposable			
Bipolar Ablator 55°,			
Non-Aspirating			
	llh	Voo	Apr 26, 2017
C2455NA	llb	Yes	Api 20, 2017
2.4mm UltrAblator			
Bipolar 55°,			
Non-Aspirating			
7205	llb	Yes	Mar 13, 2017
2.4mm Disposable			
Bipolar Ablator –			
Private Label 55°,			
Non-Aspirating			

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	BA1860NA	llb	Yes	Jan 29, 2016
	1.8mm Disposable			
	Bipolar Ablator 60°,			
	Non-Aspirating			
	C1860NA	llb	Yes	Apr 26, 2017
	1.8mm UltrAblator			• •
	Bipolar 60°,			
	Non-Aspirating			
	7206	llb	Yes	Mar 13, 2017
	1.8mm Disposable			,
	Bipolar Ablator –			
	Private Label 60°,			
	Non-Aspirating			
Forceps				
	A820	llb	Yes	*
	A821	llb	Yes	*
	A822	llb	Yes	*
	A823	llb	Yes	*
	A824	llb	Yes	*
	A825	Ilb	Yes	*
	A826	Ilb	Yes	*
	A827BP	Ilb	No	Apr 25, 2014
	A827F	Ilb	No	Apr 25, 2014 Apr 25, 2014
		llb	Yes	July 1, 2010
	A840	llb	Yes	*
	A841	llb	Yes	*
	A842	llb	Yes	
	A843	llb	Yes	*
	A844	llb	Yes	*
	A845	llb	Yes	*
Electrode Adapter				
	A905B (0.8mm)	llb	No	*
	A905B-1 (1.25mm)	llb	No	*
	A905EL (1.5mm)	IIb	No	*
Remote Switch		110	110	
	RHSW	llb	Yes	*
	RHSW-L	Ilb	Yes	*
Footswitch			163	
TOOISWIICH	A1203	llb	No	*
				*
	A1203W	IIb	No	*
	A1253	llb	No	*
	A1253-H	llb	No	*
	AR-9600FB	llb	No	
	AR-9600FM	llb	No	*
	BV-1253B	llb	No	*
	BV-1253B BV-1253BGI BV-1254B	llb llb	No No	*



	Bovie Ultimate Generator Plasma	llb	No	July 1, 2016
	Footswitch			
	BVX-JPHFS			0 1 00 0010
	<u>A803</u>	llb	No	Sept 20, 2018
Bendable Needle Electrodes Reu				E 1 0 00/0
	ELA9B	llb	Yes	Feb 6, 2012
	ELA1B	llb	Yes	Feb 6, 2012
	ELA2B	llb	Yes	Feb 6, 2012
	ELA3B	llb	Yes	Feb 6, 2012
	ELF1B	llb	Yes	Feb 6, 2012
	ELA8B	llb	Yes	Feb 6, 2012
Bendable Round Loop Electrodes				
	ELB1B	llb	Yes	Feb 6, 2012
	ELB2B	llb	Yes	Feb 6, 2012
	ELB3B	llb	Yes	Feb 6, 2012
	ELB4B	llb	Yes	Feb 6, 2012
	ELB5B	llb	Yes	Feb 6, 2012
	ELB6B	llb	Yes	Feb 6, 2012
Bendable Diamond Loop Electrod	les Reusable			
	ELC1B	llb	Yes	Feb 6, 2012
	ELC3B	llb	Yes	Feb 6, 2012
	ELC17B	llb	Yes	Feb 6, 2012
	ELC6B	llb	Yes	Feb 6, 2012
	ELC18B	llb	Yes	Feb 6, 2012
Bendable Triangle Loop Electrode	es Reusable			
~ .	ELC7B	llb	Yes	Feb 6, 2012
	ELC8B	llb	Yes	Feb 6, 2012
Bendable Ball Electrodes Reusab	le			
	ELD3B	llb	Yes	Feb 6, 2012
	ELD8B	llb	Yes	Feb 6, 2012
Bendable Scalpel Electrodes	-			
	ELE1B	llb	Yes	Feb 6, 2012
	ELE3B	llb	Yes	Feb 6, 2012
Insulated Needle Electrodes Expo				
	ELD6B	llb	Yes	Feb 6, 2012
	ELD6C	llb	Yes	Feb 6, 2012
Insulated Sclerotherapy Needles		110	100	1 05 0, 2012
	ELD41	llb	Yes	Feb 6, 2012
	ELD42	IIb	Yes	Feb 6, 2012
Disposable electrodes			100	1 00 0, 2012
	ELA2D	llb	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	llb	Yes	Feb 6, 2012

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Electrodes Assortment Pack				
	ELPK40	llb	Yes	Feb 6, 2012
Laparoscopic Instrument				
	BVX-AG3301	llb	Yes	Feb 6, 2012
	BVX-AG3301-2.5	llb	Yes	Feb 6, 2012
	BVX-AG3301R	llb	Yes	Feb 6, 2012
	BVX-AG3301R-2.5	llb	Yes	Feb 6, 2012
	BVX-AT3301	llb	Yes	Feb 6, 2012
	BVX-AT3301R	llb	Yes	Feb 6, 2012
	BVX-BB3301	llb	Yes	Feb 6, 2012
	BVX-BB3301R	llb	Yes	Feb 6, 2012
	BVX-BB4501	llb	Yes	Feb 6, 2012
	BVX-BB4501R	llb	Yes	Feb 6, 2012
	BVX-BB3301W	llb	Yes	Feb 6, 2012
	BVX-BB3301WR	llb	Yes	Feb 6, 2012
	BVX-BB4501W	llb	Yes	Feb 6, 2012
	BVX-BB4501WR	llb	Yes	Feb 6, 2012
	BVX-BD3301	llb	Yes	Feb 6, 2012
	BVX-BD3301R	llb	Yes	Feb 6, 2012
	BVX-BF3301	llb	Yes	Feb 6, 2012
	BVX-BF3301R	llb	Yes	Feb 6, 2012
	BVX-BF3302	llb	Yes	Feb 6, 2012
	BVX-BF3302R	llb	Yes	Feb 6, 2012
	BVX-CD3301	llb	Yes	Feb 6, 2012
	BVX-CD3301R	llb	Yes	Feb 6, 2012
	BVX-CF3301	llb	Yes	Feb 6, 2012
	BVX-CF3301R	llb	Yes	Feb 6, 2012
	BVX-CS3301	llb	Yes	Feb 6, 2012
	BVX-CS4501	llb	Yes	Feb 6, 2012
	BVX-DB3301	llb	Yes	Feb 6, 2012
	BVX-DB3301R	llb	Yes	Feb 6, 2012
	BVX-DN3301	llb	Yes	Feb 6, 2012
	BVX-DN3301R	llb	Yes	Feb 6, 2012
	BVX-DT3301	llb	Yes	Feb 6, 2012
	BVX-DT3301R	llb	Yes	Feb 6, 2012
	BVX-EC3301	llb	Yes	Feb 6, 2012
	BVX-EC3301R	llb	Yes	Feb 6, 2012
	BVX-EC4501R	llb	Yes	Feb 6, 2012
	BVX-FS3301	llb	Yes	Feb 6, 2012
	BVX-FS3301R	llb	Yes	Feb 6, 2012
	BVX-HS3301	llb	Yes	Feb 6, 2012
	BVX-HS4501	llb	Yes	Feb 6, 2012
	BVX-MF3301	llb	Yes	Feb 6, 2012
	BVX-MF3301R	llb	Yes	Feb 6, 2012
	BVX-ML3301	llb	Yes	Feb 6, 2012
	BVX-ML3301-2.5	llb	Yes	Feb 6, 2012
	BVX-ML3301R	llb	Yes	Feb 6, 2012
	BVX-ML3301R-2.5	llb	Yes	Feb 6, 2012

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	BVX-ML4501	llb	Yes	Feb 6, 2012
	BVX-RA3301	llb	Yes	Feb 6, 2012
	BVX-RA3301R	llb	Yes	Feb 6, 2012
	BVX-RG3301	llb	Yes	Feb 6, 2012
	BVX-RG3301R	llb	Yes	Feb 6, 2012
	BVX-SS3301	llb	Yes	Feb 6, 2012
	BVX-SS3301-2.5	llb	Yes	Feb 6, 2012
	BVX-SS3302	llb	Yes	Feb 6, 2012
	BVX-SS3303	llb	Yes	Feb 6, 2012
	BVX-SS3304	llb	Yes	Feb 6, 2012
	BVX-SS3305	llb	Yes	Feb 6, 2012
	BVX-SS3306	llb	Yes	Feb 6, 2012
	BVX-TG3301	llb	Yes	Feb 6, 2012
	BVX-TG3301R	llb	Yes	Feb 6, 2012
	BVX-VF3301	llb	Yes	Feb 6, 2012
	BVX-VF3301R	llb	Yes	Feb 6, 2012
Laparoscopic Electrodes		-		
	BVX-LL06-NS	llb	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	Ilb	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	Ilb	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	llb	Yes	June 26, 2014
	LS05	llb	Yes	June 26, 2014
	LJ07	Ilb	Yes	June 26, 2014
	LH08	llb	Yes	June 26, 2014
	LH01	llb	Yes	June 26, 2014
	LN03	llb	Yes	June 26, 2014
	BVX-LL06	llb	Yes	June 26, 2014
	BVX-LC04	llb	Yes	June 26, 2014
	BVX-LB02	llb	Yes	June 26, 2014
	BVX-LS05	llb	Yes	June 26, 2014
	BVX-LJ07	llb	Yes	June 26, 2014
	BVX-LH08	llb	Yes	June 26, 2014
	BVX-LH01	llb	Yes	June 26, 2014

Product List for Certificate No: 41312698-01 Date: November 18, 2018 Page 17 of 19



	BVX-LN03	llb	Yes	June 26, 2014
Laparoscopic Electrodes (Coated; Blue)			
	BVX-LL06T-NS	llb	No	June 20, 2013
	BVX-LC04T-NS	llb	No	June 20, 2013
	BVX-LB02T-NS	llb	No	June 20, 2013
	BVX-LS05T-NS	llb	No	June 20, 2013
	BVX-LJ07T-NS	llb	No	June 20, 2013
	BVX-LH08T-NS	llb	No	June 20, 2013
	BVX-LH01T-NS	llb	No	June 20, 2013
	BVX-LN03T-NS	llb	No	June 20, 2013
Laparoscopic Electrodes (Coated; Black;)			
	LL06BT-NS	llb	No	June 26, 2014
	LC04BT-NS	llb	No	June 26, 2014
	LB02BT-NS	llb	No	June 26, 2014
	LS05BT-NS	llb	No	June 26, 2014
	LJ07BT-NS	llb	No	June 26, 2014
	LH08BT-NS	llb	No	June 26, 2014
	LH01BT-NS	llb	No	June 26, 2014
	LN03BT-NS	llb	No	June 26, 2014
	LL06BT	llb	Yes	June 26, 2014
	LC04BT	llb	Yes	June 26, 2014
	LB02BT	Ilb	Yes	June 26, 2014
	LS05BT	llb	Yes	June 26, 2014
	LJ07BT	Ilb	Yes	June 26, 2014
	LH08BT	llb	Yes	June 26, 2014
	LH01BT	Ilb	Yes	June 26, 2014
	LN03BT	IIb	Yes	June 26, 2014
	BVX-LL06BT	Ilb	Yes	June 26, 2014
	BVX-LC04BT	Ilb	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	Ilb	Yes	June 26, 2014
	BVX-LH01BT	Ilb	Yes	June 26, 2014
	BVX-LN03BT	IIb	Yes	June 26, 2014
Suction Coagulator				
Custon Couguiator	SCH08	IIb	Yes	Feb 6, 2012
	SCH10	Ilb	Yes	Feb 6, 2012
	SCH12	Ilb	Yes	Feb 6, 2012
	SCF08	IIb	Yes	Feb 6, 2012
	SCF10	IIb	Yes	Feb 6, 2012
	SCF10	IIb	Yes	Feb 6, 2012 Feb 6, 2012
	JULIT	un	162	Feb 0, 2012

* Product added before July 1, 2010



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

Intertek Semko AB Notified Body MDD

e Chalemu

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.



MDD – Decision Report

Quality. Assured.						
	Certificate No: 41312698-01 Date: October 5, 2018 Handled by: Carolina Escobar E-mail: medtechsweden@intertek.com					
Bovie Medical Corporatio Att: Dr. Topaz Kirlew 5115 Ulmerton Road Clearwater, FL 33760 USA	n					
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