

# EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number  
41312698

Initial Certification Date  
November 2, 2003

Certificate Valid from  
July 10, 2009

Certificate Expiry Date  
November 17, 2013

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 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.

*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.*

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## Organization:

### **Bovie Medical Corporation**

5115 Ulmerton Road, Clearwater, FL 33760, USA

## Product Category:

- Cauteries
- Disposable nerve locators
- Medical light
- Electrosurgery equipment including accessories
- Ophthalmology burrs and power handles
- Nail drills and power handle

July 10, 2009

Signed date



Hans Ericsson, Acting Certification Manager MDD  
Intertek Semko AB, Kista, Sweden



# MDD -- Product List

Products included in the certificate no: 41312698  
Issued to:

Bovie Medical Corporation  
5115 Ulmerton Road  
Clearwater, FL 33760  
USA

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>
High Temperature Cauteries	AA01	IIb	Yes	
	AA03	IIb	Yes	
	AA05	IIb	Yes	
	AA09	IIb	Yes	
	AA11	IIb	Yes	
	AA17	IIb	Yes	
	AA21	IIb	Yes	
	AA25	IIb	Yes	
	AA27	IIb	Yes	
	AA29	IIb	Yes	
Ophthalmic Cauteries	AA00	IIb	Yes	
	AA02	IIb	Yes	
	AA04	IIb	Yes	
	AA90	IIb	Yes	
Replaceable Tips		IIb	Yes	
	H100	IIb	Yes	
	H101	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		
CH05	IIb	Yes		
H101-ADH	IIb	Yes		
Replaceable Tip Kits	HIT0	IIb	No	
	HIT1	IIb	No	
	DEL0	IIb	No	
	DEL1	IIb	No	
	DEL 2	IIb	No	
Nerve Locators	0003Y	IIa	Yes	



# MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Medical lights (surgical)	ST05	IIa	Yes	
	ST10	IIa	Yes	
	ST15	IIa	Yes	
Electrosurgery equipment and accessories: Generators	A800EU	IIb	No	
	A800EU-220	IIb	No	
	A900	IIb	No	
	A900EU-220	IIb	No	
	A940	IIb	No	
	A950	IIb	No	
	A950-220	IIb	No	
	A1250-220	IIb	No	
	IDS-200	IIb	No	
	IDS-300	IIb	No	
	A2250	IIb	No	
	A3250	IIb	No	
	GI-120	IIb	No	
	A1250U	IIb	No	
	GP-300	IIb	No	
VS-300	IIb	No		
Saline enhanced electrosurgical resection device	SR145L	IIb	Yes	
	SR326L	IIb	Yes	
	BOSS1215	IIb	Yes	
Electrosurgery equipment and accessories: Pencils	A801EU	IIb	No	
	A901	IIb	No	
	ESPR	IIb	No	
	ESP1	IIb	Yes	
	ESP1H	IIb	Yes	
	ESP1HS	IIb	Yes	
	ESP1N	IIb	Yes	
	ESP1HN	IIb	Yes	
	ESP6	IIb	Yes	
	ESP6H	IIb	Yes	
	ESP6HS	IIb	Yes	
	ESP6N	IIb	Yes	
	ESP6HN	IIb	Yes	
	ESP7	IIb	Yes	
	ESP7H	IIb	Yes	
ESP7HS	IIb	Yes		
ESP7N	IIb	Yes		
ESP7HN	IIb	Yes		





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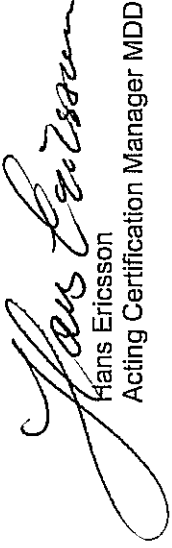
Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>
	AB05	Ila	Yes	
	0011	Ila	Yes	
	0012	Ila	Yes	
Ophthalmic Power handles	0010	Ila	No	
Nail Drill	0007	Ila	Yes	
Laparoscopic Handle	MIHNDI	Ilb	No	
	MIHNDI-NR	Ilb	No	
Laparoscopic Electrodes Tube	MI32SFT	Ilb	No	
Laparoscopic Electrode: Tip insert single use	MI32STS-DI	Ilb	Yes	
	MI32CMS-DI	Ilb	Yes	
Laparoscopic Electrode: Tip insert reusable	MI32AGG-RI	Ilb	No	
	MI32ALG-RI	Ilb	No	
	MI32ATG-RI	Ilb	No	
	MI32BCG-RI	Ilb	No	
	MI32BLD-RI	Ilb	No	
	MI32DND-RI	Ilb	No	
	MI32MYD-RI	Ilb	No	
	MI32MXD-RI	Ilb	No	
	MI32ECG-RI	Ilb	No	
	MI32JG2-RI	Ilb	No	
	MI32STS-LUI	Ilb	No	
	MI32CMS-LUI	Ilb	No	
Laparoscopic Electrode: Cartridge	MI32STS-DC	Ilb	Yes	
	MI32CMS-DC	Ilb	Yes	
	MI32AGG-DC	Ilb	Yes	
	MI32ALG-DC	Ilb	Yes	
	MI32ATG-DC	Ilb	Yes	
	MI32BCG-DC	Ilb	Yes	
	MI32MYD-DC	Ilb	Yes	
	MI32MXD-DC	Ilb	Yes	
	MI32DND-DC	Ilb	Yes	
	MI32BLD-DC	Ilb	Yes	
	MI32ECG-DC	Ilb	Yes	
	MI32JG2-DC	Ilb	Yes	



# MDD – Product List

Date of Issue: July 10, 2009

Intertek Semko AB  
Notified Body MDD



Hans Ericsson  
Acting Certification Manager 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.

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