

# EC Certificate

**PRODUCTION QUALITY ASSURANCE  
Directive 93/42/EEC on Medical Devices, Annex V**

Certificate Number  
41313069

Initial Certification Date  
November 2, 2003

Certificate Valid from  
July 10, 2009

Certificate Expiry Date  
November 17, 2013

*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.*

*Intertek Semko AB  
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medtechsweden@intertek.com*

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the Swedish national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

## Organization:

### **Bovie Medical Corporation**

5115 Ulmerton Road, Clearwater, FL 33760, USA

## Product Category:

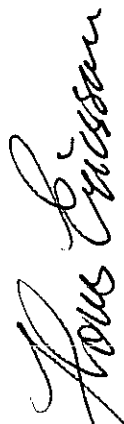
- Surgical lights and eye bubbles, Class I sterile

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

July 10, 2009

Signed date

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





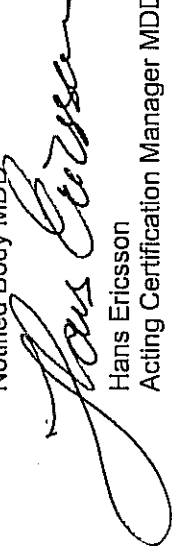
# MDD – Product List

Products included in the certificate no: 41313069  
 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>
Medical lights	SLOT PDOT	I	Yes	
Eye Bubble	0002	I	Yes	

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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