

# EC CERTIFICATION

## PRODUCTION QUALITY ASSURANCE

### Directive 93/42/EEC on Medical Devices, Annex V

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 LVFS 2003:11 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

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

**Product Category:**

Class I sterile devices

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

**Certificate Number:**

41313069-02

**Initial Certification Date:**

2 November 2003

**Certificate Valid from:**

18 November 2018

**Certificate Expiry Date:**

17 November 2023



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.

