Intertek

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
November 18, 2013

Certificate Expiry Date
November 17, 2018

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
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
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, 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

5115 Ulmerton Road, Clearwater, FL 33760, USA

Product Category:

- Lighted Orotracheal Intubation Stylets and eye bubbles, Class I sterile

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

November 15, 2013
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2008-09-01