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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

SWEDAC ACKREDITERING
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.

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MDD – Product List

Products included in the Certificate No: 41313069-02
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
Clas I sterile devices					
Lighted Orotracheal Intubation Stylets	SLOT	I	Yes		*
	PDOT				*
Handpiece Sheath	A910ST	I	Yes		Jan 29, 2016
Eye Bubble	0002	I	Yes		*
Sterile Hose Tube	786TS / Model ARVT10424	I	Yes		Mar 13, 2017
Vacuum Hose	SETWS / Model ARVTWT424	I	Yes		Mar 13, 2017
Sterile Tube and adaptor	SERFS / Model ARRF10210	I	Yes		Mar 13, 2017
Sterile Hose and adaptor	SEVL / Model ARVTVIC05	I	Yes		Mar 13, 2017
Sterile adaptor and tubing	SEPA / Model PA1025	I	Yes		Mar 13, 2017
Sterile adaptor and tubing	SEPAT / PA2010	I	Yes		July 11, 2017

* Product added before September 13, 2012.

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

Intertek Semko AB
Notified Body MDD

Peter Nermander
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.

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MDD – Decision Report

Certificate No: 41313069-02
Date: October 5, 2018
Handled by: Carolina Escobar
E-mail: medtechsweden@intertek.com

Bovie Medical Corporation
Att: Dr. Topaz Kirlew
5115 Ulmerton Road
Clearwater, FL 33760
USA

Purpose	Five year extension assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
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. All non-conformities from the activities have been closed. The five year extension assessment was performed at Intertek's office.
Scope of assessment	Class I sterile devices
Issue date of certificate	18 November 2018
Conclusions/Decisions	The scope has been amended to better reflect the scope of NB involvement. 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 V, 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