### Certificate of Registration



This is to certify that the quality management system of

### ShaoXing Haitech Medical Products Co., Ltd.

Main Site: 22-708, Jin Hu Wan, Shiji Street, Paojiang Industrial Zone, ShaoXing City, Zhengjiang Province, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 13485:2003

The quality management system is applicable to

1) Manufacturing and Distribute of Disposable Patient Plate, Disposable Skin Staple Remover, Laryngeal Airway Mask, Disposable Anesthesia Breathing Circuit, Disposable Bacterial Viral Filter, Disposable Closed Suction Catheter, Disposable Endotrached Type Holder, Endotracheal Tube, Disposable Anesthesia Puncture Kit and Disposable Irrigation Syringe; Filters / HME: Yankuear Sucher

2) Design & Development, Manufacturing and Distribute of Disposable Electrosurgical Pencils.

Certificate Number:

SCC-0040-03

initial Certification Date: Certificate Effective Date: 24 July 2015

24 July 2009

Calin Moldovean, President Intertek Testing Services NA, Ltd. -

1829, 32nd avenue, Lachine, QC, H8T 3J1, Canada







Directive 93/42/EEC on Medical Devices, Annex II (3) (OBL) FULL QUALITY ASSURANCE SYSTEM

Sertificate Number nitial Certification Date \ugust 28, 2009

pril 28, 2014 ertificate Valid from

ertificate Expiry Date 27, 2019

he certification is subject to the organization maintaining the system in compliance ith the regulations stated in its certificate, allowing illowing the contracted quirements of the Notified gular assessments and

entification number 0413

tertek Semko AB x 1103, SE-164 22 Kista, edtechsweden@intertek.com ephone +46 8 750 00 00

tertek Semko AB is a otified Body according to rective 93/42/EEC on

use the CE 0413 marking on those products listed below. aforementioned directive, and the result entitles the organization to quality assurance system conforms with the relevant provisions of the which the undersigned is subjected, transposing Annex II (with the devices via an Own Branding arrangement. We certify that the full exemption of section 4) of the Directive 93/42/EEC on medical quality assurance system has been carried out following the requirements of the Swedish national legislation, LVFS 2003:11, to We hereby declare that an examination of the under mentioned full

## Organization:

## င္ပ ShaoXing Haitech Medical Products d

City, Zhengjiang Province, CHINA 22-78, Jin Hu Wan, Shiji Street, Paojiang Industrial Zone, ShaoXing

Product Category:

Disposable Electrosurgical Pencils

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

April 28, 2014

Signed date

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

2008-09-01



# **EC** Certificate

Directive 93/42/EEC on Medical Devices, Annex V (OBL) PRODUCTION QUALITY ASSURANCE

Certificate Number 41317109

Initial Certification Date
August 28, 2009
Certificate Valid from

April 28, 2014

Certificate Expiry Date 3 27, 2019

The certification is subject to the organization maintaining their system in compliance with the regulations stated 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 04/13.

Box 1103, SE-164 22 Kista, Sweden Telephone +46 8 750 00 00 medtechsweden@intertek.com

> relevant provisions of the aforementioned legislation, and the result products listed below. entitles the organization to use the CE 0413 marking on those We certify that the production quality system conforms with the 93/42/EEC on medical devices via an Own Branding arrangement. undersigned is subjected, transposing Annex V of the Directive Swedish national legislation, LVFS 2003:11, to which the conditions - has been carried out following the requirements of the production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile We hereby declare that an examination of the under mentioned

### Organization:

# ShaoXing Haitech Medical Products Co., Ltd

City, Zhengjiang Province, CHINA 22-78, Jin Hu Wan, Shiji Street, Paojiang Industrial Zone, ShaoXing

## **Product Category:**

- Disposable Closed Suction Catheter, class Is
- Disposable irrigation Syringe, class Is

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

April 28, 2014

Signed date

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



Directive 93/42/EEC on Medical Devices, Annex V (OBL) PRODUCTION QUALITY ASSURANCE

Certificate Number 41317069 Initial Certification Date

August 28, 2009

April 28, 2014 Certificate Valid from

Certificate Expiry Date

the organization maintaining their system in compliance with the regulations stated in this certificate, allowing The certification is subject to

Notified Body according to Directive 93/42/EEC on identification number 0413 medical devices, with

Sweden Telephone +46 8 750 00 00

medtechsweden@intertek.com

following the contracted requirements of the Notified

Intertek Semko AB is a

regular assessments and

Box 1103, Intertek Semko AB SE-164 22 Kista

> products listed below. result entitles the organization to use the CE 0413 marking on those with the relevant provisions of the aforementioned legislation, and the arrangement. We certify that the production quality system conforms Directive 93/42/EEC on medical devices via an Own Branding to which the undersigned is subjected, transposing Annex V of the the requirements of the Swedish national legislation, LVFS 2003:11, production quality assurance system has been carried out following We hereby declare that an examination of the under mentioned

### Organization:

# ShaoXing Haitech Medical Products Co., Ltd

City, Zhengjiang Province, CHINA 22-708, Jin Hu Wan, Shiji Street, Paojiang Industrial Zone, ShaoXing

## **Product Category:**

- Disposable Bacterial Viral Filter
- Disposable Anesthesia Breathing Circuit
- Filters / HME
- Yankuear Suction Sets
- Laryngeal Airway Mask
- Endotracheal Tube

Anesthesia Mask

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

April 28, 2014

Signed date

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