

# CERTIFICATE OF REGISTRATION

This is to certify that the 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 registered by Intertek as conforming to the requirements of:

## ISO 13485:2016

The 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 Endotracheal Tube Holder, Endotracheal Tube, Disposable Anesthesia Puncture Kit and Disposable Irrigation Syringe; Filters / HME; Yankuear Suction Sets.
- 2) Design & Development, Manufacturing and Distribute of Disposable Electrosurgical Pencils.

**Certificate Number:**

SCC-0040-04

**Initial Certification Date:**

24 July 2009

**Certificate Issue Date:**

23 July 2018

**Certificate Expiry Date:**

23 July 2021



A handwritten signature in black ink, appearing to read "Calin Moldovean", is written over a horizontal line.

**Calin Moldovean**  
President, Business Assurance

Intertek Testing Services NA Ltd.,  
1829, 32nd avenue, Lachine, QC, H8T 3J1,  
Canada



# 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 via an Own Branding arrangement. 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:**

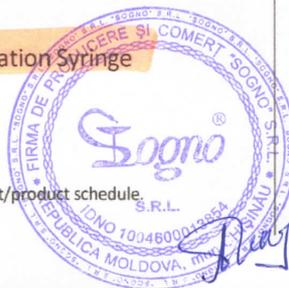
## ShaoXing Haitech Medical Products Co., Ltd

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

**Product Category:**

- Disposable Closed Suction Catheter, Disposable irrigation Syringe

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



**Certificate Number:**

41317109-01

**Initial Certification Date:**

28 August 2009

**Certificate Valid from:**

28 April 2019

**Certificate Expiry Date:**

27 April 2024



Accred. no. 1003  
Certification of  
Management  
Systems  
ISO/IEC 17021-1

**Bob Andersson**

Certification Authority MDD

Intertek Semko AB, Kista, Sweden

4 April 2019

**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.





# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

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

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

**Organization:**

## ShaoXing Haitech Medical Products Co., Ltd

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

**Product Category:**

- Disposable Electrosurgical Pencils



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

**Certificate Number:**

41317059 -01

**Initial Certification Date:**

28 August 2009

**Certificate Valid from:**

28 April 2019

**Certificate Expiry Date:**

27 April 2024



**Bob Andersson**

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

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**Signed Date**

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