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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

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President, Business Assurance

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

Digitally signed by Iarovoi Petru
Date: 2020.04.15 13:52:41 EEST
Reason: MoldSign Signature
Location: Moldova

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. * REPUBLICA MOLDOVA, mun. Chișinău * IDNO 1004600013...

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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 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.

Certificate Number:
41317069-01

Initial Certification Date:
28 August 2009

Certificate Valid from:
28 April 2019

Certificate Expiry Date:
27 April 2024

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

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 Bacterial Viral Filter, Disposable Anesthesia Breathing Circuit, Filters/HME, Laryngeal Airway Mask, Endotracheal Tube, Anesthesia Kit and Needle

- Yankuear Suction Sets

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

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.

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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 via an Own Braning arrengement. 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.

Certificate Number:
41317109-01

Initial Certification Date:
28 August 2009

Certificate Valid from:
28 April 2019

Certificate Expiry Date:
27 April 2024

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

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.

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.

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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

SWEDAC ACKREDITERING
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.