Certificate of Registration

Digitally signed by Iarovoi Petru
Date: 2019.02.01 16:54:07 EET
Reason: MoldSign Signature
Location: Moldova

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 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-0040-03
Initial Certification Date: 24 July 2009
Certificate Effective Date: 24 July 2015

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

SCC Accredited CB-MS
SCCM Accredite SCC

EC Certificate

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

Certificate Number
31317059

Initial Certification Date
August 28, 2009

Certificate Valid from
April 28, 2014

Certificate Expiry Date
April 27, 2019

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and allowing 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 full 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 II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. 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

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

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, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2008-09-01

EC Certificate

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

Certificate Number
41317109

Initial Certification Date
August 28, 2009

Certificate Valid from
April 28, 2014

Certificate Expiry Date
April 27, 2019

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 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

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

Product Category:

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

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

2006-09-01

EC Certificate

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

Certificate Number
41317069

Initial Certification Date
August 28, 2009

Certificate Valid from
April 28, 2014

Certificate Expiry Date
April 27, 2019

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 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

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

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

2008-09-01