

Intertek



EC Certificate

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

Certificate Number
1317059

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.

Interlek Senko AB is a notified Body according to Directive 93/42/EEC on medical devices, with certification number 0413.

Interlek Senko AB
Box 1103, SE-164 22 Kista,
Sweden
Telephone +46 8 750 00 00
adtechsweden@interlek.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
Interlek Senko AB, Kista, Sweden

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
1 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 2003:1, 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

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
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medtechsweden@intertek.com

EC Certificate

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

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