

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. 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:

IHSS Ltd

Main Site: Unit 5, CT3 Business Park, Cooting Road, Aylesham, Kent
CT3 3EP, United Kingdom

Product Category:

- The moist heat sterilization of surgical instrument sets, packs and supplementary instruments

* Previously certified by Intertek AMTAC (NB0473) to date 26 June 2018

Certificate Number:

41377186-01

Initial Certification Date:

9 October 2009*

Certificate Valid from:

9 October 2019

Certificate Expiry Date:

27 May 2024



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

Bob Andersson

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2 September 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.



Certificate No: 41377186-01
Date: 2 September 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

IHSS Ltd
Attn: Dean Burand
Unit 5, CT3 Business Park
Cooting Road
Aylesham, Kent CT3 3EP
United Kingdom

Purpose Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.

Activity Certification audit was performed 20 February 2019 in Aylesham by Charles Bright.

Scope of assessment The moist heat sterilization of surgical instrument sets, packs and supplementary instruments, Class I(s)

Result 0 non conformities were noted during the audit.

Certificate Valid from 9 October 2019

Conclusions/Decisions Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".

Follow-up assessments Follow-up assessments are going to be performed once a year.

Appeals Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD



Bob Andersson
Certification Authority MDD