intertek
Total Quality. Assured.

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 9, Premier Park, Park Royal, London NW10 7NZ, United Kingdom

Product Category:

- Sterile instrument sets, packs and supplementary instruments

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

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

Certificate Number:
41377244-01

Initial Certification Date:
29 May 2009*

Certificate Valid from:
29 May 2019

Certificate Expiry Date:
27 May 2024

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

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

23 May 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.

intertek
Total Quality. Assured.

MDD – Decision Report

Certificate No: 41377244-01
Date: 23 May 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

IHSS Ltd
Attn: Dean Burand
Unit 9, Premier Park,
Park Royal,
London NW10 7NZ
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 V.
Activity	Certification audit was performed 6 February 2019 in Park Royal by by Charles Bright.
Scope of assessment	Sterile instrument sets, packs and supplementary instruments.
Result	1 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	29 May 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

Peter Nermander
Certification Authority MDD