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 3, Westpoint Business Park, Larkhill Trading Estate, New Hythe Lane, Aylesford, Maidstone, Kent, ME20 6XX, United Kingdom

Product Category:

- Sterile instrument sets, packs and supplementary instruments.

* Previously certified by Intertek AMTAC (NB0473) to date 05 February 2019

Certificate Number:
41377510-00

Initial Certification Date:
06 February 2019*

Certificate Valid from:
06 February 2019

Certificate Expiry Date:
05 February 2024

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

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

06 February 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.