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

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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.