intertek
Total Quality. Assured.

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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. 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:

FHC, Inc

Main Site: 1201 Main Street, Bowdoin,
Maine 04287, USA

Product Category:

- WayPoint Stereotactic System implant tools, surgical tools, software, platform adapters and platform biopsy kits
- microTargeting Guideline 4000
- Class I sterile devices

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

Certificate Number:
41313871-02

Initial Certification Date:
18 June 2006

Certificate Valid from:
12 December 2018

Certificate Expiry Date:
18 June 2021

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

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

12 December 2018
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.