

# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

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

**Certificate Number**  
41313871-01

**Initial Certification Date**  
18 June, 2006

**Certificate Valid from**  
June 19, 2016

**Certificate Expiry Date**  
June 18, 2021

*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.*

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Ackred. nr 1003  
ISO/IEC 17021

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**

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
- microTargeting Electrode cable (class I sterile)
- Sterile Drapes (class I sterile)

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

June 17, 2016

Signed date

Mats Premfors, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden