

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41313871

Initial Certification Date
18 June, 2006

Certificate Valid from
March 25, 2010

Certificate Expiry Date
June 18, 2011

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 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.

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 Semko AB
Box 1103, SE-164 22 Kista,
Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com*

Organization:

FHC, Inc

1201 Main Street, Bowdoin, ME 04287, USA

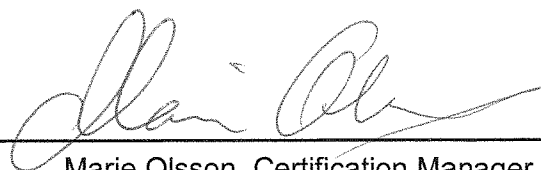
Product Category:

- WayPoint Stereotactic System implant tools, surgical tools, software, platform adapters and platform biopsy kits
- microTargeting Guideline 4000
- microTargeting Electrode cable (class I sterile)

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

March 25, 2010

Signed date



Marie Olsson, Certification Manager MDD
Intertek Semko AB, Kista, Sweden

Certificate No: 41313871
Date: March 25, 2010
Handled by: Marie Olsson
E-mail: medtechsweden@intertek.com

FHC, Inc
Keri Seitz
1201 Main Street
Bowdoin, ME 04287
USA

Purpose Revision of the wording of the product category of the certificate.
“Stereotactic System ...” is changed to “WayPoint Stereotactic System...”

Scope of assessment Annex II, point 3: 41313871
- WayPoint Stereotactic System implant tools, surgical tools, software, platform adapters and platform biopsy kits
- microTargeting Guideline 4000
Class II a
- microTargeting Electrode cable
Class I sterile

Issue date of certificate March 25, 2010

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 II, point 3 will be issued. The Certificate is valid for products specified in the product list

Follow-up assessments Follow-up assessments are going to be performed once a year.

Appeals Any appeal shall be submitted to the manager of Medical Regulatory Services, Intertek Semko AB, 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



Marie Olsson
Certification Manager MDD