

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41318560

Initial Certification Date
March 24, 2010

Certificate Valid from
March 24, 2010

Certificate Expiry Date
March 24, 2015

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.

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Organization:

FHC, Inc

1201 Main Street, Bowdoin, ME 04287, USA

Product Category:

- microTargeting electrodes
- microTargeting insertion tubes

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

For placing the class III devices covered by this certificate on the market, an EC design-examination certificate according to MDD Annex II (4) is required.

March 24, 2010

Signed date



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

Certificate No: 41313871, 41318560,
41318570
Date: March 24, 2010
Handled by: Marie Olsson
E-mail: medtechsweden@intertek.com

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


Purpose	Assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II. Revision of existing certificate and issue of new certificates due to classification changes. The 2007/47/EC changes rule 6 and as a consequence the FHC's devices in contact with the CNS become class III. The products now becoming class III have since June 18, 2006 and until now been covered by EC certificate 41313871 for Annex II, point 3, the products have now been removed from the systems. This has led to changes in that product list. A separate Annex II, point 3 certificate will now be issued for the class III devices as well as a Design Examination certificate for Annex II, point 4.
Activity	A Design Dossier review covering the microTargeting electrodes and the microTargeting insertion tubes has been performed off-site by Dr Drury and by Hans Ericsson and the dossier was accepted 19 March 2010 (review report dated 19 March 2010). The review included the requirements of 2007/47/EC.
Scope of assessment	<u>Annex II, point 3: 41313871</u> - 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 <u>Annex II, point 3: 41318560</u> - microTargeting electrodes - microTargeting insertion tubes Class III <u>Annex II, point 4: 41318570</u> - microTargeting electrodes - microTargeting insertion tubes Class III
Issue date of certificate	March 24, 2010
Conclusions/Decisions	Referring to the above Certificates 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/revised. The Certificates are valid for products specified in the product list to each certificate. Also a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II, point 4 will be issued and application of the CE-mark may be done when

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the company's own procedures for CE-marking are fulfilled. The product identification and details are stated in the Annex to the Certificate.

- 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