EC Certificate

EC DESIGN-EXAMINATION CERTIFICATE
Directive 93/42/EEC on Medical Devices, Annex II (4)

Certificate Number
41318570-02

Initial Certification Date
March 24, 2010

Certificate Valid from
September 25, 2015

Certificate Expiry Date
March 24, 2020

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

We hereby declare that a design examination has been carried out on the devices(s) listed hereafter following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed hereafter conforms with the relevant provisions of Annex II section 4 of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products*.

Organization:

FHC, Inc

1201 Main Street, Bowdoin, Maine 04287, USA

Product Category:

- microTargeting electrodes

- microTargeting insertion tubes

*For CE marking the class class III devices covered by this certificate an EC certificate according to Annex II section 3 is also required.

September 23, 2015
Signed date

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

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