EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II

Certificate Number
41318560-02

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.

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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:

- 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. These products are highlighted in the product list /product schedule.

September 23, 2015
Signed date

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