

# EC Certificate

**FULL QUALITY ASSURANCE SYSTEM**

**Directive 93/42/EEC on Medical Devices, Annex V**

**Certificate Number**  
41314794

**Initial Certification Date**  
August 25, 2004

**Certificate Valid from**  
August 25, 2009

**Certificate Expiry Date**  
August 25, 2014

*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 an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the Swedish national legislation to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

**Organization:**

**FHC, Inc.**

1201 Main Street, ME 04287, Bowdoin, USA


**Product Category:**

Sterile Drapes  
Class I, sterile

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

August 11, 2009

Signed date

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