EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41319092

Initial Certification Date
January 19, 2011

Certificate Valid from
March 26, 2012

Certificate Expiry Date
January 19, 2016

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 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.

Organization:

Hammarplast Medical AB

Box 2069, Kartåsgatan 8, 531 02 Lidköping

Product Category:

- Orthopaedic bone pin, non-biodegradable
- Bone staple
- Manual surgical saw, flexible
- Pneumatic Tourniquet

March 26, 2012
Signed date

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