EC Certificate

FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41319092-01

Initial Certification Date
January 19, 2011

Certificate Valid from
January 20, 2016

Certificate Expiry Date
January 19, 2021

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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Ackred. nr 1003
ISO/IEC 17021

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:

Hammarplast Medical AB

Kartåsgatan 8, SE-531 40 Lidköping, Sweden

Product Category:

- Manual surgical saw, flexible
- Pneumatic Tourniquet
- Medicine measures, disposables, Class I measuring

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

December 18, 2015
Signed date

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

2015-09-30