

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II (3)

Certificate Number
41316708

Initial Certification Date
November 25, 2008

Certificate Valid from
September 7, 2009

Certificate Expiry Date
November 25, 2013

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.

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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Organization:

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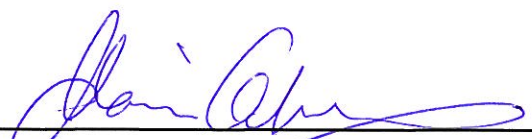
Product Category:

- Vacuum electrode system for ECG

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

September 7, 2009

Signed date



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