



EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41313650

Initial Certification Date
June 6, 2000

Certificate Valid from
June 6, 2010

Certificate Expiry Date
June 6, 2015

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.

*Intertek Semko AB
Box 1103, SE-164 22 Kista,
Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com*

Organization:

Neoventa Medical AB

Ågatan 32, SE-431 35 Mölndal, Sweden

Product Category:

- Fetal ECG monitors and electrodes

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

June 4, 2010

Signed date


Hans Ericsson, Acting Certification Manager MDD
Intertek Semko AB, Kista, Sweden