

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

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

Certificate Number
41314263

Initial Certification Date
September 28, 2004

Certificate Valid from
May 7, 2014

Certificate Expiry Date
May 6, 2019

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.

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:

Masimo Sweden AB

Svärdvägen 15, SE-182 33 Danderyd, Sweden

Product Category:

Gas Monitoring Devices

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

April 25, 2014

Signed date



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