

EC Certificate

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Certificate Number
41313831-01

Initial Certification Date
March 22, 2001

Certificate Valid from
July 12, 2016

Certificate Expiry Date
March 22, 2021

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:

TERATECH Corporation

77-79 Terrace Hall Avenue Burlington, Massachusetts 01803, USA

Product Category:

- Portable Medical Ultrasound Imaging Equipment

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



Ackred. nr 1003
ISO/IEC 17021

July 12, 2016

Signed date



Göran Nerby, Certification Authority MDD
Intertek Semko AB, Kista, Sweden