

EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE (Annex V of the Directive 93/42/EEC on Medical Devices)

No. 41314021

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned legislation.

Manufacturer:

Ursus Konsult AB
Arsenalsgatan 4
SE-111 47 Stockholm
Sweden

Product category:

Rotex Screw Needle Biopsy Instrument

Date of expiry:

17 December 2011

Stockholm
17 December 2006

Intertek Semko AB
Notified Body MDD

Original certificate issued
17 December 2001


Marie Olsson
Certification Manager MDD

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek ETL SEMKO

2004-05-14