

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex II of the Directive 93/42/EEC on Medical Devices)

No. 41313199

We hereby declare that an examination of the under mentioned full 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 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 legislation.

Manufacturer: Capintec, Inc.
540 Alpha Drive
Pittsburgh, PA 152 38
USA

Product category: Thyroid uptake systems

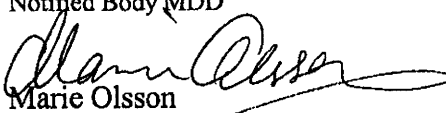
Date of expiry: 8 December 2010

The Certificate is valid for the devices which are stated in the present MDD – Product list

Stockholm
3 February 2006

The original certificate issued on
8 December 2000

Intertek Semko AB
Notified Body MDD


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.

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41313219
Date: 2006-03-22

Capintec, Inc.
540 Alpha Drive
PA 152 38
Pittsburgh
USA

Activity Review of the Technical File for products for compliance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC)

Review based on LVFS 2003:11 and Recommendation NB-MED/2.5.1/REC 5, Technical Documentation

Reviewed by Peter Lymeus

Review dates 2006-03-16

Location Kista, Sweden

Product and Class Captus 3000, Class IIa

Conclusion The technical documentation for the above-mentioned product, including corrective actions, has been reviewed and found to contain the information prescribed in LVFS 2003:11. The information has been found to be plausible and credible.

Intertek Semko AB
Notified Body MDD


Marie Olsson

