

EC Certificate

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

Certificate Number
41316298

Initial Certification Date
June 18, 2008

Certificate Issue Date
June 18, 2013

Certificate Expiry Date
June 18, 2018

We hereby declare that an examination of the under mentioned production 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 V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, 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.

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Organization:

AMICI Inc.

518 Vincent Street, Spring City, PA 19475, USA

Product Category:

- Radioaerosol systems

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

June 13, 2013

Signed date



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