EC Certificate

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC on Medical Devices, Annex V

Certificate Number
41314102

Initial Certification Date
August 21, 2008

Certificate Issue Date
August 22, 2013

Certificate Expiry Date
August 21, 2018

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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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.

Organization:

AB Ulax

Box 5096, Merkuriusgatan 8, SE-591 05 Motala, Sweden

Product Category:

- HME Products (Heat and Moisture Exchangers)
- Bacterial / Viral Filters
- Tubing for connection of the HME

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

August 14, 2013
Signed date

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

2007-01-24