Intertek

EC Certificate

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

Certificate Number
41314061

Initial Certification Date
December 11, 2001

Certificate Valid from
March 28, 2012

Certificate Expiry Date
December 11, 2016

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 - restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions - has been carried out following the requirements of the Swedish national legislation 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:

Universal First Aid Europe AB

Arendalsvägen 33E, SE-434 39 Kungsbacka, Sweden

Product Category:

- Irrigation kit, Eye

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

March 28, 2012
Signed date

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

2008-09-01