

# EC Certificate

## PRODUCTION QUALITY ASSURANCE

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

**Certificate Number**  
41310145

**Initial Certification Date**  
December 8, 1995

**Certificate Valid from**  
December 9, 2015

**Certificate Expiry Date**  
December 8, 2020

*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.*

*Intertek Semko AB  
Box 1103, SE-164 22 Kista,  
Sweden  
Telephone +46 8 750 00 00  
medtechsweden@intertek.com*



Ackred. nr 1003  
ISO/IEC 17021

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 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:

**AKLA AB**

Enhagsslingan 21 A, 187 40 Täby Sweden  
Box 534, 182 15 Danderyd, Sweden

#### Product Category:

- Sterile medical devices for wound management,  
Class I sterile

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

December 7, 2015

Signed date

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