

# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full 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 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 directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

#### Organization:

## AKLA AB

Main Site: Box 534, Enhagsslingan 21 A, SE-182 15 Danderyd, Sweden

#### Product Category:

- Burn gel
- Burn and wound dressings

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

#### Certificate Number:

41314724-01

#### Initial Certification Date:

27 May 2004

#### Certificate Valid from:

28 May 2019

#### Certificate Expiry Date:

27 May 2024



#### Bob Andersson

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

23 April 2019

#### Signed Date

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

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.

