

# EC Certificate

**FULL QUALITY ASSURANCE SYSTEM**

**Directive 93/42/EEC on Medical Devices, Annex II (3)**

**Certificate Number**  
41314724

**Initial Certification Date**  
May 27, 2004

**Certificate Valid from**  
May 28, 2014

**Certificate Expiry Date**  
May 27, 2019

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.

*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*

## Organization:

**AKLA AB**

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.

May 16, 2014

Signed date

  
Hans Ericsson, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

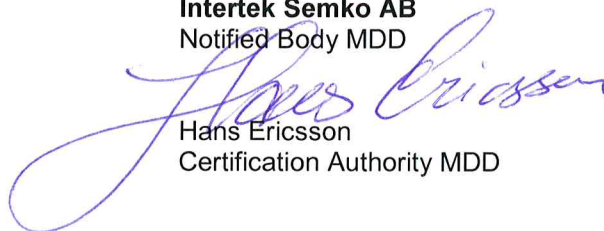
Products included in the certificate no: 41314724  
 Issued to: **AKLA AB**  
 Box 534  
 Enhagsslingan 21 A  
 SE-182 15 Danderyd  
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
BurnFree Sterile Burn and Wound Dressing	5x5 cm / 0202	IIb	Yes	-	*
	5 x 15 cm / 0206	IIb	Yes	-	*
	10 x 10 cm / 0404	IIb	Yes	-	*
	10 x 40 cm / 0416	IIb	Yes	-	Nov 4, 2010
	20 x 20 cm / 0808	IIb	Yes	-	*
	20 x 45 cm / 0818	IIb	Yes	-	Nov 4, 2010
	30 x 30 cm / 1212	IIb	Yes	-	*
	30 x 40 cm / 1216	IIb	Yes	-	Nov 4, 2010
40 x 60 cm / 1624	IIb	Yes	-	Nov 4, 2010	
BurnFree Pain relieving gel	3.5 gram / SD	IIa	No	-	*
	5 gram / SD-5ml	IIa	No	-	Nov 4, 2010
	59 ml / 2B-48	IIa	No	-	Nov 4, 2010
	Squeeze bottle 118 ml / 4B-24	IIa	No	-	*
BurnFree Aerosol Can	45 ml	IIa	No	-	*
	50 ml / SC-50ML				Nov 4, 2010
	75 ml	IIa	No	-	*
	100 ml	IIa	No	-	*

\* Date added before November 4, 2010.

Date of Issue: May 16, 2014

**Intertek Semko AB**  
 Notified Body MDD



Hans Ericsson  
 Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Product list for certificate no: 41314724

Date: May 16, 2014

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Intertek Semko AB

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