

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.



Products included in the certificate no: 41314724-01
Issued to: **AKLA AB**
Box 534
Enhagsslingan 2
SE-182 15 Danderyd
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Burn and Wound Dressings					
	First Aid FOR BURNS 5 x 5 cm / 94371	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 5 x 15 cm / 94375	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 10 x 10 cm / 94373	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 20 x 20 cm / 94377	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 30 x 30 cm / 94379	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 10 x 40 cm / 94365	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 20 x 45 cm / 94366	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 40 x 60 cm / 94380	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 30 x 40 cm / 94367	Iib	Yes	-	Apr 29, 2016
	First Aid FOR BURNS 100 x 100 cm / 94381	Iib	No	-	Apr 29, 2016
	First Aid FOR BURNS 100 x 200 cm / 94383	Iib	No	-	Apr 29, 2016
	BURNMED 5 x 5 cm / 94371	Iib	Yes	-	Mar 16, 2018
	BURNMED 5 x 15 cm / 94375	Iib	Yes	-	Mar 16, 2018
	BURNMED 10 x 10 cm / 94373	Iib	Yes	-	Mar 16, 2018
	BURNMED 20 x 20 cm / 94377	Iib	Yes	-	Mar 16, 2018
	BURNMED 30 x 30 cm / 94379	Iib	Yes	-	Mar 16, 2018
	BURNMED 10 x 40 cm / 94365	Iib	Yes	-	Mar 16, 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	BURNMED 20 x 45 cm / 94366	Ilb	Yes	-	Mar 16, 2018
	BURNMED 40 x 60 cm / 94380	Ilb	Yes	-	Mar 16, 2018
	BURNMED 30 x 40 cm / 94367	Ilb	Yes	-	Mar 16, 2018
	BURNMED 100 x 100 cm / 94381	Ilb	No	-	Mar 16, 2018
	BURNMED 100 x 200 cm / 94383	Ilb	No	-	Mar 16, 2018
<i>Burn gel</i>					
	First Aid FOR BURNS 3,5 gram / 94370	Ila	No	-	Apr 29, 2016
	First Aid FOR BURNS 59 ml / 94399	Ila	No	-	Apr 29, 2016
	First Aid FOR BURNS 118 ml / 94400	Ila	No	-	Apr 29, 2016
	BURNMED 3,5 gram / 94370	Ila	No	-	Mar 16, 2018
	BURNMED 59 ml / 94399	Ila	No	-	Mar 16, 2018
	BURNMED 118 ml / 94400	Ila	No	-	Mar 16, 2018

* Date added before November 4, 2010.

Sign Date: 23 April 2019
Valid Date: 28 May 2019

Intertek Semko AB
Notified Body MDD


Bob Andersson
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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Date: 28 May 2019
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Certificate No: 41314724-01
Date: 23 April 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

AKLA AB
Attn: Eva Janmark
Box 534
Enhagsslingan 2
SE-182 15 Danderyd
Sweden

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 17 October 2018 in Danderyd by Per Bergström, Gabriel Johansson and Göran Nerby. The technical file was reviewed by Sofia Blad and Iffat Noor at Intertek's office.
Scope of assessment	- Burn gel, Class IIa - Burn and wound dressings, Class IIb
Result	3 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	28 May 2019
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD



Bob Andersson
Certification Authority MDD