

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:

Orkla Care AB

Main Site: Svetsarvägen 15, Solna, Sweden

Postal Address: Box 1336, SE-171 26 Solna, Sweden

Product Category:

- Quick Healing plasters
- Hydrocolloid Dressings
- Wound care products
- Dressings
- Adhesive bandages
- Wet wipes
- Burn Gel
- Bandages
- Eye/Wound Wash

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

Certificate Number:

41315275-06

Initial Certification Date:

17 November 2005

Certificate Valid from:

11 December 2018

Certificate Expiry Date:

10 December 2023



Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

27 November 2018

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: 41315275-06
 Issued to: **Orkla Care AB**
 Visiting address:
 Svetsarvägen 15
 Solna, Sweden
 Postal address:
 Box 1336
 SE-171 26 Solna
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Quick Healing plasters	51000016 Salvelox Aqua Mix	Ila	No	44990	April 8, 2016
	51030055 Salvequick Aqua Block 16	Ila	No	44990	Nov 21, 2017
	51030056 Salvequick Aqua Block 16	Ila	No	44990	Nov 21, 2017
	51030057 Salvelox Aqua Block 16	Ila	No	44990	Nov 21, 2017
	540324 Salvequick Quick Healing Aqua Block	Ila	No	44990	April 25, 2012
	540355 Salvelox Aqua Block Strips	Ila	No	44990	May 31, 2012
	621855 Salvelox Aqua Block 12	Ila	No	44990	Feb 22, 2010
	621824, 621856 Salvequick Aqua Block 12	Ila	No	44990	Feb 22, 2010
	621924, 984429, 984430 Salvequick Aqua Block Kids	Ila	No	44990	May 28, 2013
	621955 Salvelox Aqua Block Kids	Ila	No	44990	May 28, 2013
	658124,986789 Salvequick Med Aqua Cover Kids	Ila	No	44990	May 28, 2013
	658165 Salvelox Med Aqua Cover Kids 5	Ila	No	44990	Oct 18, 2013
	658225, 658055 Salvequick Med Aqua Cover 5	Ila	No	44990	Feb 3, 2011
	658265 Salvelox Med Aqua Cover 5	Ila	No	44990	Oct 18, 2013
	658524 Salvequick Med Aqua Cover XXL 5	Ila	No	44990	Jan 9, 2015

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 Date: 14 April 2021
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Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	658555 Salvelox Med Aqua Cover XXL 5	Ila	No	44990	Jan 9, 2015
	673510 Salvequick Quick Healing 50p	Ila	No	44990	June 28, 2010
	984181 Plaster Aqua Block Small	Ila	No	44990	Feb 22, 2010
	984182 Aqua Block Jumbo	Ila	No	44990	Feb 22, 2010
	51030131 Salvelox Aqua Block Kids	Ila	No	44990	Jun 11, 2019
	51030147 Salvequick Aqua Block Kids	Ila	No	44990	Jun 11, 2019
	51030132 Salvelox Aqua Block Mini	Ila	No	44990	Jun 11, 2019
	51030133, 51030149 Salvequick Aqua Block Mini	Ila	No	44990	Jun 11, 2019
	51030166 Salvelox Med Aqua Cover 3XL	Ila	No	44990	Aug 14, 2019
	51030167 Salvequick Med Aqua Cover 3XL	Ila	No	44990	Aug 14, 2019
	Norgesplaster Scankvikk vanttett bandasje 5,4 x 7,6 cm	Ila	No	44990	Mar 18, 2021
	Norgesplaster Scankvikk vanttett bandasje 7,9 x 9,7 cm	Ila	No	44990	Mar 18, 2021
Hydrocolloid Dressings	986503 Hydrocolloid plaster large (bulk)	Ila	No	43186	Feb 22, 2010
	986505 Hydrocolloid plaster small (bulk)	Ila	No	43186	Feb 22, 2010
	986509 Hydrocolloid plaster white paper (bulk)	Ila	No	43186	Feb 17, 2010
	602225 Salvequick Blister Prevention Heels	Ila	No	43186	Feb 17, 2010
	602226 Salvequick Blister Prevention Heel & Toes	Ila	No	43186	Feb 17, 2010
	602227 Salvequick Blister Prevention Toes	Ila	No	43186	Feb 17, 2010

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Intertek Semko AB

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Registered in Sweden: No SE556024059901, Registered office: As address

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	310404 Doctor San	Ila	No	43186	Feb 17, 2010
	602235 Salvequick Blister Prevention Heels	Ila	No	43186	Mar 12, 2010
	602236 Salvequick Blister Prevention Heel & Toes	Ila	No	43186	Mar 12, 2010
	602237 Salvequick Blister Prevention Toes	Ila	No	43186	Mar 12, 2010
	602625 Salvelox Blister Prevention Heels	Ila	No	43186	Mar 12, 2010
	602626 Salvelox Blister Prevention Heels & Toes	Ila	No	43186	Mar 12, 2010
	602627 Salvelox Blister Prevention Toes	Ila	No	43186	Mar 12, 2010
	602230 Salvequick Blister Prevention Heels	Ila	No	43186	Sept 21, 2012
	51030136 Salvequick Foot Care Blister Plaster Heels	Ila	No	43186	Jun 11, 2019
	51030259 Norgesplaster Forebyggende Gnagsårplaster Tå 6	Ila	No	43186	Oct 22, 2020
	51030263 Norgesplaster Forebyggende Gnagsårplaster Hæl 5	Ila	No	43186	Oct 22, 2020
	Deliplus Hidrocoloide	Ila	No	43186	Mar 18, 2021
Wound care products	658226 Salvequick Med Antibact Cover 5	Ila	No	47378	June 5, 2012
	658365 Salvelox Antibact Cover 5	Ila	No	47378	Oct 18, 2013

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Dressings	984018 Salvequick Sterile Compress	I	Yes	48131	*
	984019 Salvequick Sterile Compress	I	Yes	48131	*
	51618171 Metallized dressing	I	Yes	48131	Sep 25, 2015
	51030266 Salvequick Med Sterile Compresses M	I	Yes	48131	Jan 06, 2021
	51030267 Salvequick Med Sterile Compresses XL	I	Yes	48131	Jan 06, 2021
	51030265 Salvelox Med Sterile Compresses M	I	Yes	48131	Jan 06, 2021
	51030264 Salvelox Med Sterile Compresses XL	I	Yes	48131	Jan 06, 2021
	4120 Norgesplaster Scansoft compress 5x7,5cm	I	Yes	48131	Jan 06, 2021
	4121 Norgesplaster Scansoft compress 10x7,5cm	I	Yes	48131	Jan 06, 2021
	Adhesive bandages	582042 Salvequick Maxi Cover 5	I	Yes	34864
658024 658255 Salvequick Med Maxi Cover 5		I	Yes	34864	Dec 13, 2013
658065 Salvelox Med Maxi Cover 5		I	Yes	34864	*
658424 Salvequick Med Maxi Cover XXL 5		I	Yes	34864	Jan 9, 2015
658455 Salvelox Med Maxi Cover XXL 5		I	Yes	34864	Jan 9, 2015
673512 Salvequick Maxi Cover 50		I	Yes	34864	Dec 13, 2013
984074 Plaster Maxi cover		I	Yes	34864	*
Salvequick Plastic plaster (refill)		I	Yes	34864	Sep 25, 2015
Salvequick Textile plaster (refill)		I	Yes	34864	Sep 25, 2015

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	Salvequick Detectable plaster (refill)	I	Yes	34864	Sep 25, 2015
	Salvequick Detectable Fingertip/Regular (refill)	I	Yes	34864	Sep 25, 2015
	51030165 Salvequick Med Maxi Cover 3XL	I	Yes	34864	Aug 14, 2019
	51030168 Salvelox Med Maxi Cover 3XL	I	Yes	34864	Aug 14, 2019
	Norgesplaster Scankvikk bandasje beige 5,4 x 7,6 cm	I	Yes	34864	Mar 18, 2021
	Norgesplaster Scankvikk bandasje hvit 5,4 x 7,6 cm	I	Yes	34864	Mar 18, 2021
	Norgesplaster Scankvikk bandasje 5 x 9,7 cm	I	Yes	34864	Mar 18, 2021
	Norgesplaster Scankvikk bandasje 20 x 9,7 cm	I	Yes	34864	Mar 18, 2021
Wet Wipes	3239,3227 Salvequick Wound Cleanser	Ila	Yes	61695	Sep 25, 2015
	323700 Salvequick Wound Cleanser	Ila	Yes	61695	Sep 25, 2015
	51030282 SalveloxMED Wound Cleanser Wipes	Ila	Yes	61695	Jan 06, 2021
	51030283 SalvequickMED Wound Cleanser Wipes	Ila	Yes	61695	Jan 06, 2021
Burn Gel	901903 Burn Cover	Ila	Yes	47764	July 2, 2014
	901900, 51618575 Burn Gel dressing	Ila	Yes	47693	Oct 23, 2015
	901901 Burn Gel spray	Ila	Yes	47694	Oct 23, 2015
	51011005 (OBL) Cederroth Burn Gel 100ml	Ila	No	58108	Nov 26, 2018
Bandages	1910 Cederroth 4-in-1	I	Yes	59022	Sep 25, 2015
	1911 Cederroth 4-in-1 Mini	I	Yes	59022	Sep 25, 2015
	922385 Army Dressing	I	Yes	59022	Sep 25, 2015

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
Eye / Wound Wash	51030002 Salvequick (OBL) Wound Cleanser Sterile Spray	IIb	Yes	64871	July 25, 2016
	51030003 Salvelox (OBL) Wound Cleanser Sterile Spray	IIb	Yes	64871	July 25, 2016
	7251,7221,7255, 725200 Cederroth Eye Wash	I	Yes	11655	Sep 25, 2015
	726000 Cederroth Eye & Wound Cleansing Spray 150 ml (OBL)	IIa	Yes	63285	Feb 29, 2012

* Product added before February 22, 2009.

Date of Issue: 14 April 2021

Intertek Semko AB
Notified Body MDD



Peter Nermander
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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