



## Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Orkla Wound Care AB / Orkla Care AB
Manufacturer address and contact details	Box 1336, SE-171 26 Solna, Sweden
Single Registration Number (SRN) (if available)	SE-MF-000021041

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	Intertek Semko AB
Notified body number (if applicable)	0413
Directive Certificate number(s) to which this confirmation is made (if applicable)	41315275-06
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	10 December 2023
End date of extended validity/transition period	31 December 2028

Postal address  
Orkla Care AB  
Box 1336  
SE-171 26 Solna  
www.cederroth.com

Visiting address  
Svetsarvägen 15  
Solna  
Sweden  
www.salvequick.com

Telephone  
010 142 64 00  
International  
+46 (0)10 142 64 00

Organizational No:  
556052-5478  
VAT No:  
SE556052547801

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate** as listed above

- Directive Certificate covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

*Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.



➤ **Device(s) as listed in the attached Product List**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Full Company Name: Orkla Wound Care AB / Orkla Care AB

Location & Date: Solna, September 19<sup>th</sup> 2023

Signature

A handwritten signature in blue ink that reads "Johanna Brinck".

Johanna Brinck  
Head of Regulatory and Quality  
Person Responsible for Regulatory Compliance

Regulatory\_WC@orkla.com

---

Postal address  
Orkla Care AB  
Box 1336  
SE-171 26 Solna  
www.cederroth.com

Visiting address  
Svetsarvägen 15  
Solna  
Sweden  
www.salvequick.com

Telephone  
010 142 64 00  
International  
+46 (0)10 142 64 00

Organizational No:  
556052-5478  
VAT No:  
SE556052547801

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

Product List for Certificate No: 41315275-06  
 Date: 14 April 2021  
 Page 1 of 6

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



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.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.