

# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

### EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

## Orkla Wound Care AB

Svetsarvägen 15, SE-171 26 Solna, Sweden

Manufacturer SRN: SE-MF-000021041

### Scope:

- Class I Sterile Devices
- Quick-healing plasters

**Certificate Number:**

28620123341

**Initial Certification Date:**

8 April 2022

**Date of Certification Decision:**

8 April 2022

**Certificate Issue Date:**

8 April 2022

**Certificate Expiry Date:**

7 April 2027

Insert Signature



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Brian Mather  
Certification Authority, MDR  
Intertek Medical Notified Body AB,  
Torshamnsgatan 43,  
Box 1103, SE-164 22 Kista, Sweden

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

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**PRODUCT LIST FOR CERTIFICATE**

*See attached Product List*

**EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD00054-01 Orkla Wound Care - Salvequick Med Aqua Cover Kids
Audit Report Reference	Stage 1 audit ACTY-2022-528784
	Stage 2 audit ACTY-2022-528787

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

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