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.

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

Orkla Wound Care AB

Svetsarvägen 15, SE-171 26 Solna, Sweden

Manufacturer SRN: SE-MF-000021041

Scope:

- Class I Sterile Devices
- Quick-healing plasters

Insert Signature

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

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.

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

Brian Mather
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