intertek
Total Quality. Assured.

EC CERTIFICATION

EU Quality Management System Certificate

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

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

For Class Is devices, this assessment is restricted to the aspects relating to the conformity of the devices with the sterility requirements as appropriate.

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:

- Non-active devices for wound care
- Wound cleansing spray
- Sterility aspects of devices as detailed in attached product list.

Certificate Number:
28620123341

Revision:
02

Initial Certification Date:
8 April 2022

Certificate Decision Date:
8 May 2025

Certificate Issue Date:
8 May 2025

Certificate Expiry Date:
7 February 2027

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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

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**
	TD0054-0003 Burn Cover Limited TD Review (Sterilization)
	TD00054-004 Cederrroth Eye Wash 235 ml Limited TD Review (sterilization)
	TD00054-005 Cederroth Eye & Wound Cleansing spray
Audit Report Reference	**Stage 1 audit ACTY-2022-528784**
	Stage 2 audit ACTY-2022-528787
	Surveillance 1 ACTY-2022-538661
	Surveillance 2 ACTY-2022-538669

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620123341	8 April 2022	Initial Issue
28620123341-01	11 February 2025	Change to scope

Certificate Number:
28620123341

Revision:
02

Initial Certification Date:
8 April 2022

Certificate Decision Date:
8 May 2025

Certificate Issue Date:
8 May 2025

Certificate Expiry Date:
7 February 2027

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.