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 technical documentation has been carried out following the requirements of Regulation (EU) 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.

Aurena Laboratories AB

Fjärrviksvägen 22, SE-653 50 Karlstad, Sweden

Manufacturer SRN: SE-MF-000002890

Scope:

- Non-sterile solutions and gels for skin care
- Sterile saline solutions (wound wash, nasal sprays, and eye and ear solutions)

Certificate Number:
28620131862

Revision:
04

Initial Certification Date:
28 October 2022

Date of Certification Decision:
10 June 2026

Certificate Issue Date:
10 June 2026

Certificate Expiry Date:
27 October 2027

Curtis Riley
Head of Notified Body
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.

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Total Quality. Assured.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00131-01 Burn Gel**
	TD00131-02 Wound and Eye Wash, Isotonic, NaCl, Buffered
	TD00131-03 Ear Spray, NaCl, Buffered
Audit Report Reference	**Stage 1 DELTA audit ACTY-2021-501561**
	Stage 2 DELTA audit ACTY-2021-501562
Change Notice Reference	**CN00131-021**
	CN00131-022
	CN00131-026
	MISC00131-007

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620131862	28 October 2022	Initial certification
28620131862-01	09 August 2023	Addition of product group
28620131862-02	01 October 2024	Correction of scope
28620131862-03	18 February 2025	Correction of scope
28620131862-04	10 June 2026	Correction to expiration date

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