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:
28620131862

Initial Certification Date:
28 October 2022

Date of Certification Decision:
28 October 2022

Certificate Issue Date:
28 October 2022

Certificate Expiry Date:
19 November 2026

Aurena Laboratories AB

Fjärrviksvägen 22, SE-653 50 Karlstad, Sweden

Manufacturer SRN: SE-MF-000002890

Scope:

Sterile saline solution.

Brian Mather
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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.