EU Declaration of Conformity

Manufacturer:	Aurena Laboratories AB Fjärrviksvägen 22 653 50 Karlstad Sweden
SRN (Single Registration Number):	SE-MF-000002890
Reference and name of the product:	Versions of Aurena Wound and Eye Wash, with reference numbers: REF 2002-1 REF 2002-2 REF 2002-3
Intended use:	Sterile isotonic saline solution for rinsing/cleansing of eye and wounds.
Basic UDI-DI:	7332343200017D
Device classification:	Class IIa, rule 4 according to annex VIII
Notified Body MDR: Notified Body Identification number:	Intertek Medical Notified Body (IMNB) 2862
EC certificate number: EC certificate expiry date:	28620131862 19 November 2026

This declaration of conformity is issued under the sole responsibility of Aurena Laboratories. We hereby declare that the medical devices specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices with assessment route Annex IX. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by IMNB.

All supporting documentation is retained at the premises of the manufacturer.

See Appendix 1 for reference to harmonized standards and/or to common specifications.

Signature for Aurena Laboratories AB:

Anders Bared (Aug 14, 2023 13:10 GMT+2)

Anders Bared
Person Responsible for Regulatory Compliance

Place and date:

Karlstad, 2023-08-14