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

This declaration of conformity is issued under the sole responsibility of Aurena Laboratories. We hereby declare that the medical device(s) 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 (Feb 13, 2023 12:07 GMT+1)

Anders Bared
Person Responsible for Regulatory Compliance

Place and date:

Karlstad, 2023-02-13

Appendix 1

Reference to harmonized standards and/or to common specifications:

Standard/Other directive/Guideline	Name	Version
SS-EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	2021
SS-EN ISO 20417	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	2021
SS-EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-11)	2020
SS-EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016 + A11:2021
SS-EN ISO 14644-1	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016
SS-EN ISO 14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2016
SS-EN ISO 17141	Cleanrooms and associated controlled environments - Biocontamination control	2020
SS-EN ISO 14971:2020	Medical devices – Application of risk management to medical devices (ISO 14971:2019	2020 + A11:2021
SIS-CEN ISO/TR 24971	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)	2020
SIS-CEN ISO/TR 20416	Medical devices - Post-market surveillance for manufacturers (ISO/TR 20416:2020)	2020
SS-EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015 + A1:2020
SS-EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	2020
SS-EN ISO 11137-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	2015 + A2:2019
SS-EN ISO 11137-2	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	2015
SS-EN ISO 11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	2018
SS-EN ISO 11737-2	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	2020

MEDDEV 2.7/1	Clinical evaluation: Guide for manufacturers and notified bodies	Rev. 4
MSBFS 2018:1 (ADD)	Föreskrifter om aerosolbehållare (Regulation on aerosol containers)	2018
MSBFS 2022:3 (ADR-s)	Föreskrifter om transport av farligt gods på väg och i terräng (Regulation on transport of dangerous goods)	2023
Ph. Eur. Monograph for Sodium chloride, 0193		Current version
Ph. Eur. Monograph for Water, Purified, 0008		Current version
Ph. Eur. Monograph for Water for injections, 0169		Current version
Ph. Eur. Monograph for Sodium dihydrogen phosphate dihydrate, 0194		Current version
Ph. Eur. Monograph for Sodium hydroxide, 0677		Current version
Ph. Eur. Monograph for Calcium chloride dihydrate, 0015		Current version
Ph. Eur. Monograph for Potassium chloride, 0185		Current version

TD-1465 DoC Wound and Eye Wash REF 2002_v4

Final Audit Report 2023-02-13

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