

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 Nasal Spray, Isotonic, with reference numbers:
REF 2010-1
REF 2010-2
REF 2010-3
REF 2010-4
REF 2010-5
REF 2010-6

Intended use: To clear and moisturize the nasal mucosa/cavity.

Basic UDI-DI: 7332343200067P

Device classification: Class IIa, rule 21 according to annex VIII

Notified Body MDR: Intertek Medical Notified Body (IMNB)
Notified Body Identification number: 2862

EC certificate number: 28620131862
EC certificate expiry date: 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

Appendix 1

Reference to harmonized standards and/or to common specifications:

Standard/Other directive/Guideline	Version
SS-EN ISO 13485	2016 + A11:2021
EN ISO 14971	2019
SS-EN ISO 15223-1	2021
SS-EN ISO 20417	2021
ISO 10993-1	2018
SS-EN ISO 14644-1	2016
SS-EN ISO 14644-2	2016
SS-EN 17141	2020
SIS-CEN ISO/TR 24971	2020
SIS-CEN ISO/TR 20416	2020
SS-EN 62366-1	2016 + A1:2020
SS-EN ISO 11607-1	2020 + A11:2022
SS-EN ISO 11137-1	2015 + A2:2019
SS-EN ISO 11137-2	2015 + A1:2023
SS-EN ISO 11737-1	2018 + A1:2021
SS-EN ISO 11737-2	2020
MEDDEV 2.7/1	Rev 4
MSBFS 2018:1 (ADD)	2018
MSBFS 2022:3 (ADR-S)	2023
Ph. Eur. Monograph Sodium chloride, 0193	04/2021
Ph. Eur. Monograph Water, Purified, 0008	04/2018
Ph. Eur. Monograph Water for injections, 0169	04/2017
Ph. Eur. Monograph Sodium dihydrogen phosphate dihydrate, 0194	01/2021
Ph. Eur. Monograph Sodium hydroxide, 0677	01/2017
Ph. Eur. Monograph Calcium chloride dihydrate, 0015	01/2021
Ph. Eur. Monograph for Potassium chloride, 0185	04/2021






TD-1469 DoC REF 2010, V2

Final Audit Report

2023-08-14

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