

**EU DECLARATION OF CONFORMITY
REGULATION 2017/745**

MANUFACTURER	STE PHARMACEUTICALS, S.L.U
ADDRESS	AVDA. UNIVERSITAT AUTONOMA, 13 PARC TECNOLOGIC DEL VALLES 08290 CERDANYOLA DEL VALLES SPAIN
SRN	ES-MF-000000144
PRODUCT	Type ref.: PL0090 Description: ISOTONIC SALINE SOLUTION NASAL SPRAY WITH HYALURONIC ACID AND DEXPANTHENOL 20ml Trade names: (Annex I)
BASIC UDI-DI	843654262PL00908Z
EMDN CODE	Q030103
GENERIC INTENDED PURPOSE	Spray nasal solution for the irrigation and treatment of the nasal passages.
CLASSIFICATION	Class IIa (MDR Annex VIII, Rule 21)
CONFORMITY ASSESSMENT ROUTE	ANNEX XI PART A Regulation 2017/745
NB	0051 IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43, 20138 – MILANO, Italy
Num.	Certificate N: 002/MDR
Valid until	2030-12-04

We herewith declare, under own responsibility, that the medical device covered by the present Declaration is in conformity with Regulation 745/2017 including compliance with related General Safety and Performance Requirements.

Signature




**STE
PHARMACEUTICALS, S.L.U.**
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Juan Jané
President

Date **05/08/2026**

Sede central / Headquarters

Avda. Universitat Autònoma, 13 Parc Tecnològic del Vallès - 08290 Cerdanyola del Vallès, Barcelona – Spain. +34 935 923 100

Planta producción / Production plant

Ctra. De Valls, TV-2034 Km 6. 43886 Vilabella. Tarragona, Spain. +34 977 620 168

www.stepharmaceuticals.com

Type ref.: **PL0090**

Description: **ISOTONIC SALINE SOLUTION NASAL SPRAY WITH HYALURONIC ACID AND DEXPANTHENOL 20ml**

ANNEX I: TRADE NAMES

FREENOSE
RESPYVITAL
RESPYSANA
PRONARYL
NASALKID ALERGIA
X NASAL
AUVOIN
RONOSE ® HYALURONIC PLUS +1 YEAR
Aldiamed Nasenspray
Hydronase Nasal Spray
ELYSIUM® HIALURONSAVAS ORRSpray
PANTENOLLAL

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