

**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.: PL0033_120_Soft Description: HYPERTONIC SEA WATER NASAL SPRAY SOFT FORCE 120ml Trade names: (Annex I)
BASIC UDI-DI	843654262PL00338M
EMDN	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.**
 Av. Universitat Autònoma, 13
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 08290 Cerdanyola del Vallès
 Barcelona – Spain
 NIF B-62152335

Juan Jané
Chairman

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-2004 Km 6, 43886 Vilabella, Tarragona, Spain, +34 977 620 168

www.stepharmaceuticals.com

Type ref.: **PL0033_120_Soft**

Description: **HYPERTONIC SEA WATER NASAL SPRAY SOFT FORCE 120ml**

ANNEX I: TRADE NAMES

FREENOSE
LINKMARINE
MARISOL
FREZYMAR
NAZOMARIN
DR. MAX SEA WATER SPRAY BABY
SUAVINEX
CLEAN NOSE
AUVOIN BABY & JUNIOR
NENÄSUIHKE 120 ML
Woda morska hipertoniczna
ELYSIUM® HIPERTÓNÍÁS
TENGERVIZES ORRSPRAY

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