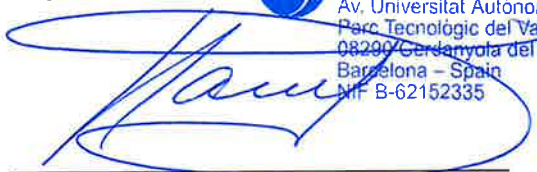


**EU DECLARATION OF CONFORMITY  
REGULATION 2017/745**

|                                    |                                                                                                                                    |
|------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>MANUFACTURER</b>                | STE PHARMACEUTICALS, S.L.U                                                                                                         |
| <b>ADDRESS</b>                     | AVDA. UNIVERSITAT AUTONOMA, 13<br>PARC TECNOLOGIC DEL VALLES<br>08290 Cerdanyola del Valles<br>SPAIN                               |
| <b>SRN</b>                         | ES-MF-000000144                                                                                                                    |
| <b>PRODUCT</b>                     | Type ref.: <b>PL0032_120_Soft</b><br>Description: <b>ISOTONIC SEA WATER NASAL SPRAY SOFT FORCE 120ml</b><br>Trade names: (Annex I) |
| <b>BASIC UDI-DI</b>                | 843654262PL00328K                                                                                                                  |
| <b>EMDN</b>                        | Q030103                                                                                                                            |
| <b>GENERIC INTENDED PURPOSE</b>    | Spray solution for the irrigation and treatment of the nasal passages.                                                             |
| <b>CLASSIFICATION</b>              | Class IIa (MDR Annex VIII, Rule 21)                                                                                                |
| <b>CONFORMITY ASSESSMENT ROUTE</b> | ANNEX XI PART A Regulation 2017/745                                                                                                |
| <b>NB</b>                          | 0051 IMQ<br>ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.<br>Via Quintiliano, 43, 20138 – MILANO, Italy                          |
| <b>Num.</b>                        | Certificate N: 002/MDR                                                                                                             |
| <b>Valid until</b>                 | 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  
 Parc Tecnològic del Vallès  
 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-2034 Km 6. 43886 Vilabella. Tarragona, Spain. +34 977 620 166

[www.stepharmaceuticals.com](http://www.stepharmaceuticals.com)

Type ref.: **PL0032\_120\_Soft**

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

#### ANNEX I: TRADE NAMES

|                                            |
|--------------------------------------------|
| FREENOSE                                   |
| LINKMARINE                                 |
| FRIMAR                                     |
| NOSONEK                                    |
| FREZYMAR                                   |
| RONOSE                                     |
| CYCLEAR                                    |
| METODE                                     |
| DELMAR                                     |
| MARISOL                                    |
| NAZOMARIN                                  |
| NORMOMAR                                   |
| ORVISIN                                    |
| Dr. Max Sea Water Spray Baby               |
| MULTIMER                                   |
| SOLIMAR                                    |
| ELYSIUM® IZOTÓNÍAS TENGERVIZES<br>ORRSPRAY |

#### Sede central / Headquarters

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#### Planta producción / Production plant

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