EU DECLARATION OF CONFORMITY
REGULATION 2017/745

MANUFACTURER	PHARMALINK, S.L
ADDRESS	AVDA. UNIVERSITAT AUTONOMA, 13 PARC TECNOLOGIC DEL VALLES 08290 CERDANYOLA DEL VALLES SPAIN
SRN	ES-MF-000000144
PRODUCT	Type ref.: **PL0075** Description: **ANTI ALLERGY NASAL SPRAY 20ML** Trade names: (Annex I)
BASIC UDI-DI	843654262TNXZ
EMDN CODE	Q030103
CLASSIFICATION	Class IIa (MDR Annex VIII, Rule 5 and 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	2025-12-10

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.

COMMON SPECIFIATIONS
Common specifications and/or the standards applied for demonstration of the conformity are detailed in Annex II.

Signature

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12/12/2022

Juan Jané
President

Date

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Type ref.: **PL0075**
Description: **ANTI ALLERGY NASAL SPRAY 20ML**

ANNEX I: TRADE NAMES

FREENOSE
PHYSIOLOGICA
RESPYVITAL
RESPYSANA
PRONARYL
HUMER RHINITE ALLERGIQUE SPRAY/ HUMER Allergic Rhinitis Spray

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Annex II: COMMON SPECIFICATIONS AND STANDARDS

Quality System
UNE-EN ISO 13485:2016
General Safety Standard
UNE-EN ISO 14971:2020
UNE-EN ISO 62366-1:2015/A1:2020
ISO 10993-1:2018
UNE-EN-ISO 10993-12:2013
ISO 15223:2021
UNE-EN ISO 1041:2009+A1:2014

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