

Nous,
We,

Laboratoire de la Mer
ZAC de La Madeleine
Avenue du Général Patton
35400 Saint-Malo (FRANCE)

garantissons et déclarons, sous notre seule responsabilité, que les dispositifs médicaux de classe IIa « Solution stérile isotonique ou hypertonique à base d'eau de mer, pour le lavage des fosses nasales, conditionnée en spray », de marques listées sur l'addendum du présent document, sont conformes aux exigences de l'annexe I de la Directive 93/42/CEE et du Code de la Santé Publique Français.

guarantee and declare, under our sole responsibility, that all class IIa medical devices "Sterile isotonic or hypertonic seawater based solution for nasal cavities cleansing, in spray" trademarks listed on the addendum of this document, comply with the requirements of Annex I of Directive 93/42/EEC and the French Public Health Code.

Cette déclaration est basée sur les éléments suivants:

This declaration is based on the following elements:

- Dossier technique MD_Reg_02 établi selon l'annexe I de la directive 93/42/CEE
Technical dossier MD_Reg_02 established according to the annex I of the Directive 93/42/EEC
- Certificat CE n°10214 d'approbation du système d'assurance qualité de la production délivré par l'organisme notifié n°0459 (LNE/G-MED).
CE certificate n° 10214 of approval of Production Quality Assurance System delivered by the Notified Body n°0459 (LNE/G-MED).

Le système de management de la qualité du Laboratoire de la mer est certifié NF EN ISO 13485. Le certificat a été délivré par le LNE/GMED (certificat n°9930).


The quality management system of Laboratoire de la mer is NF EN ISO 13485 certified. The certificate has been delivered by LNE/GMED (certificate n°9930).

La validité du présent certificat est soumise à une vérification périodique.

The validity of the certificate is subject to periodic verification.

Valable jusqu'au / Expiry date: 26 Mai 2024 (inclus) / May 26, 2024 (included)

Fait à Saint-Malo,
Written in Saint-Malo,

22/02/22


Annabelle HERVÉ
Responsable Affaires Réglementaires
Regulatory Affairs Manager

Identification des dispositifs / Identification of devices

Nom de marque / Trade name	Numéro du modèle/ Model number	Code OH / OH reference
Isotonic references		
Physiomer Baby 60ml	LABMER-001/A-01	OH1502060, OH1647060
Otrivin Natural Baby 115ml	LABMER-001/A-02	OH1637115
Respimer Baby 115ml		OH1304115 OH1543115, OH1836115
Rhinomer F0 115ml		OH1170115, OH1171115
Sinoclear Baby 115ml		OH1224115
Physiomer Baby 115ml		OH0903115, OH0920115, OH0925115, OH1003115, OH1026115, OH1113115, OH1129115, OH1335115, OH1419115, OH1731115, OH1738115, OH1801115, OH1806115, OH1814115, OH1844115, OH1927115, OH1951115, OH2051115
Delufen La Mer™ Baby 115 mL		OH2172115
Physiomer Kids 115ml		LABMER-001/A-03
Rhinomer F1 115ml	OH0065115, OH0074115, OH0088115	
Delufen La Mer™ Kids 115 mL	OH2173115	
Physiomer Baby 135ml	LABMER-001/A-04	OH1019135, OH1157135, OH1903135
Physiomer Kids 135ml	LABMER-001/A-05	OH1067135, OH1857135
Rhinomer F1 135ml		OH1106135, OH1174135
Becocleanse 135ml		OH2094135
Respimer Normal/Gentle Jet 135ml		OH1309135 OH1544135, OH1837135
Physiomer Normal/Gentle Jet 135ml	LABMER-001/A-07	OH0031135, OH0049135, OH0642135, OH0904135, OH0922135, OH0938135, OH0939135, OH1024135, OH1103135, OH1108135, OH1126135, OH1148135, OH1721135, OH1745135, OH1802135, OH1807135, OH1809135, OH1815135, OH1845135, OH1904135, OH1928135, OH2053135
Physiomer Spray 135ml		OH0047135
Rhinomer F2 135ml		OH0026135, OH0036135, OH0067135, OH0075135, OH0089135



DECLARATION CE DE CONFORMITE DM de Classe IIa
CE CONFORMITY DECLARATION of MD Class IIa

Nom de marque / Trade name	Numéro du modèle/ Model number	Code OH / OH reference
Isotonic references		
Delufen La Mer™ Classic 135 mL		OH2175135
Otrivin Natural 135ml	LABMER-001/A-08	OH1638135
Rhinomer F3 135ml	LABMER-001/A-09	OH0027135, OH0037135, OH0076135, OH0090135
Rhinomer F1 180ml	LABMER-001/A-10	OH1334180
Rhinomer F2 180ml	LABMER-001/A-11	OH1336180, OH1824180
Rhinomer F3 180ml	LABMER-001/A-12	OH1337180, OH1825180
Physiomer Normal/Gentle Jet 210ml	LABMER-001/A-13	OH1954210
Otrivin Natural 210ml	LABMER-001/A-14	OH1639210
Physiomer Strong Jet 210ml	LABMER-001/A-15	OH00043210, OH0643210, OH0942210, OH1043210, OH1107210, OH1128210, OH1474210, OH1722210, OH1810210, OH1847210, OH1853210, OH1905210, OH2054210



DECLARATION CE DE CONFORMITE DM de Classe IIa
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Nom de marque / Trade name	Numéro du modèle/ Model number	Code OH / OH reference
Hypertonic references		
Physiomer Baby Hypertonic 60ml	LABMER-002/B-01	OH1367060, OH1371060, OH1401060, OH1557060, OH1926060, OH2056060
Respimer Baby Hypertonic 60ml		OH1439060 OH1545060, OH1839060
Physiomer Baby Hypertonic 115ml	LABMER-002/B-02	OH1339115
Nasalmer Baby Hypertonic 125ml	LABMER-002/A-01	OH1165125
Respimer Décongestion Bébé 125ml		OH2139125
Nasalmer Junior Hypertonic 125ml	LABMER-002/C-01	OH1442125
Respimer Décongestion Enfant 125ml		OH2138125
Nasalmer Adult Hypertonic 125ml	LABMER-002/C-02	OH1164125
Respimer Décongestion Adulte 125ml		OH2137125
Becocleanse Plus 135ml	LABMER-002/B-04	OH2095135
Physiomer Hypertonic 135ml		OH004112135, OH0923135, OH0934135, OH1028135, OH1045135, OH1056135, OH1102135, OH1125135, OH1150135, OH1441135, OH1723135, OH1746135, OH1803135, OH1846135, OH1925135, OH1953135, OH2055135
Sinoclear Hypertonic 135ml		OH1223135, OH1628135
Respimer Hypertonic 135ml		OH1307135 OH1546135, OH1838135
Delufen La Mer™ Hypertonic 135 mL		OH2174135
Physiomer Allergy		OH21102135