

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 | | 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 |

| 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 |

| 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 |