No. 34775

NATIONAL EVALUATION CENTER OF QUALITY & TECHNOLOGY IN HEALTH S.A. (EKAPTY)
13-15 Smyrnis Street, 16562 Glyfada, GREECE
tel. +302132026200, fax: +302109615454, www.ekapty.gr
EKAPTY is a Notified body according to Council Directive 93/42/EEC concerning medical devices, identification No. 0653

EC CERTIFICATE
PRODUCTION QUALITY ASSURANCE

We hereby certify that the below named manufacturer has established and maintains a quality assurance system according to the requirements of Directive 93/42/EEC, Annex V, and its transposition in Greek legislation, for the manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Certificate No. 301011039

This certificate is issued in replacement of Certificate No. 301001039 due to the change of legal representative.

Manufacturer: GEROLYMATOS INTERNATIONAL S.A.
Facility: 13, Asklipiou Street, 14568 Kryoneri Attiki GREECE
Products: NASAL SOLUTIONS
Devices Classification: IIa
Date of first issue: 01.04.2011
Current issue date: 29.11.2016
Valid until: 3.8.2020
Audit report: 200011039

H. Papadakis (Signed)
President and Managing Director


REPUBLIQUE HELLENIQUE
MINISTERE DES AFFAIRES ETRANGERES


REPUBLIQUE
MINISTERE DES

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4);
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When these terms and conditions are complied with, the manufacturer may issue an EC declaration of conformity and legally affix the CE 0653 mark.

- - -

True translation of the attached Greek original.
Athens, 18-May-17
Eleni Kontopidou

REPUBLIQUE HELLENIQUE
MINISTERE DES AFFAIRES ETRANGERES
Vu pour legalisation de la signature ci-dessus
du Traducteur du Ministère des Affaires
Etrangères ayant traduit le texte ci-annexé

Athènes le, 18 MAY 2017

PAR DELEGATION DU MINISTRE
Le Directeur p.m.

Pavlidis Ioannis
Admin. Secretary

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia..... Việt Nam .....
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà)..... PAVLIDIS IOANNIS .....ký
has been signed by
3. với chức danh..... Viên chức lãnh sự .....
acting in the capacity of
4. và con dấu của..... Bộ ngoại giao Hy Lạp .....
bears the seal/stamp of

Được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. Tại ..... Athens ..... 6. Ngày 05/09/2017
at
7. Cơ quan cấp..... Đại sứ quán Việt Nam tại Hy Lạp .....
by
8. Số 369/..... CNLS/HPHLS
No

Ký tên và đóng dấu
Signature and seal/stamp
Thạm tán Công sứ

Phạm Hữu Dực

C.H.X.H.C.N VIỆT NAM ĐỘC LẬP - TỰ DO - HẠNH PHÚC
ĐẠI SỨ QUÁN HY LẠP

ΕΠΙΣΗΜΗ ΜΕΤΑΦΡΑΣΗ TRADUCTION OFFICIELLE OFFICIAL TRANSLATION

No. 08804-1/1

HELLENIC REPUBLIC
NATIONAL ORGANIZATION FOR MEDICINES
MESOGEION ST., 155 62 CHOLARGOS
Webpage: www.eof.gr

Directorate of Products Evaluation
Department of Sanitary Material Evaluation
Information: V. Safra
Tel. 2132040324

Cholargos, 11-01-2017
Reference No.: **60537**

TO: GEROLYMATOS INTERNATIONAL S.A
No. 13 Asklipiou St.
14568 Kryoneri of Attica

CERTIFICATE OF RE-ENTRY WITH THE REGISTRY OF MANUFACTURERS OF MEDICAL DEVICES

Category I

(Supplementary)

Taking into consideration:

1. The Joint Ministerial Decision No. ΔΥ8δ/Γ.Π.οικ.130648/30-08-2009, Official Gazette of the Government of the Hellenic Republic B/2198/2-10-2009 "Concerning the harmonization of the Hellenic Legislation with the Directive 93/42/EEC/14-6-1993 of the Council of the European Union" as it is currently in effect,
2. Your application **No. 60537/29-07-2016**, for supplementary entry with the Registry of Manufacturers of Medical Devices and the required supporting documents attached to it (with reference No. 74719, 74720/12-10-2016, 79310/01-11-2016, & 96977, 96978, 96979/16-12-2016).
3. The previous certificate of your re-entry **No. 7244/20-02-2015** with the Registry of Manufacturers of Medical Devices of the National Organization for Medicines with expiry date 23-02-2020.

WE CERTIFY

Your supplementary entry with the Registry of Manufacturers of Medical Devices of the National Organization for Medicines, according to those specified in article 14 of


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the relevant Joint Ministerial decision ΔΥ8δ/Γ.Π.οικ.130648/30-08-2009/Official Gazette of the Government of the Hellenic Republic B/2198/2-10-2009, with particulars as follows:

MANUFACTURER	GEROLYMATOS INTERNATIONAL S.A.
ADDRESS	No. 145 Dimokrartias Ave., 13672, Acharnes of Attica No. 13 Asklipiou St., 14568, Kryoneri of Attica
Telephone numbers	210 2465121-4, 210 3500800
Fax	210 3500900
Web address:	www.gerolymatos-int.com
E-mail address:	info@gerolymatos-int.com

REGISTRY No. (*): I 600 02 2020

(*) The Registry Number consists of the characterization (I = Category or OO (ΕΠ)= On order), the Code and the Date of expiry of your Registration (02/2020).

PRODUCTS OF CATEGORY I:

Serial No.	PRODUCTS	GMDN
1	SINOMARIN MINI 30 ml spray (Hypertonic sea water solution for nasal use)	36671
2	OTICLEAN by SINOMARIN spray for auricular use	12300
3	SINOMARIN ORECCHI spray for auricular use	12300
4	EARINSE by SINOMARIN 30 ml spray (Hypertonic sea water solution for auricular use)	12300
5	ISOMARIN spray (Isotonic sea water solution for nasal use)	36671
6	SINOMARIN MINI 50 ml spray (Hypertonic sea water solution for nasal use)	36671
7	EARINSE FOR KIDS by SINOMARIN 30 ml spray (Hypertonic sea water solution for auricular use)	12300


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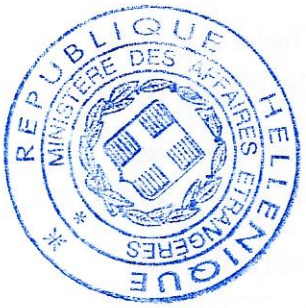
8	SINOMARIN Cold & Flu Relief 30 ml spray (Hypertonic sea water solution for nasal use)	36671
9	SINOMARIN EAR CARE Adults 30 ml spray (Hypertonic sea water solution for auricular use)	12300
10	SINOMARIN EAR CARE Children 30 ml spray (Hypertonic sea water solution for auricular use)	12300
11	**Sinomarin Plus Algae Cold & Flu Relief nasal spray 30 ml** (Hypertonic sea water solution for nasal use)	36671
12	**Sinomarin Plus Algae Allergy relief nasal spray 30 ml** (Hypertonic sea water solution for nasal use)	36671
13	**Sinomarin Dry Nose Relief nasal spray 30 ml** (Hypertonic sea water solution for nasal use)	36671

This certificate constitutes a supplementary entry for the products appearing in bold letters.

The aforesaid products of your company, at the time of their placing on the market, should bear the marking CE (article 17 of Ministerial Decision ΔΥ8δ/Γ.Π.οικ.130648/30-08-2009/Official Gazette of the Government of the Hellenic Republic B/2198/2-10-2009). **In case of unjustified placement of marking CE, article 18 of the same Ministerial Decision shall be put into effect.**

The Manufacturer, pursuant to Annex VII, paragraph 2, of Ministerial Decision ΔΥ8δ/Γ.Π.οικ.130648/30-08-2009/Official Gazette of the Government of the Hellenic Republic B/2198/2-10-2009, prepares a technical file with the technical documentation described at point 3 of the same Annex. Such file together with the Declaration of Conformity must be at the disposal of the National Organization for Medicines (ΕΟΦ) for inspection, for a period of time not less than five years since the day the last product was manufactured.


REPUBLIQUE HELLENIQUE
MINISTERE DES AFFAIRES ETRANGERES

The entry with the Registry of Manufacturers of Medical Devices of Category I, is conducted in application of article 14 of Ministerial Decision/ ΑΥ88/Γ.Π.οικ.130648/30-08-2009/Official Gazette of the Government of the Hellenic Republic B/2198/2-10-2009, is based on the Declaration of Conformity you have submitted and it does not constitute any kind of approval of quality, safety and efficiency of the product. The classification of the products in cartegory I is made by the Manufacturer, according to the classification rules of Annex IX. This classification may be reviewed following an evaluation of the technical file by the National Organization for Medicines (ΕΟΦ).

Your registration is valid through **23-02-2020** (date of expiry of initial certificate of entry/ re-entry with five-year duration).

Two (2) months prior to the elapse of the five-year period of time and provided that you continue manufacturing the said products, you must proceed to re-entry by submitting the relevant supporting documents to the National Organization for Medicines (ΕΟΦ).

Every alteration in the particulars of the certificate of registration must be declared with the National Organization for Medicines (ΕΟΦ) by submitting a new application for amendment and/or supplementation of the previous one.

This certificate invalidates all previous ones.

THE DEPUTY HEAD
OF THE DIRECTORATE OF PRODUCTS EVALUATION
(M. ORFANOU)

Attested for its accuracy.
The Head of the General Secretariat
Sealed and sgd (Despoina KONTOGIANNI)
(Round seal of the Hellenic Republic – Ministry of Health –
National Organization for Medicines (ΕΟΦ).

True translation from the attached Greek original document.
The translator: Mitropoulou Eleni 13th February 2017

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ, ΥΠΟΥΡΓΕΙΟ ΕΞΩΤΕΡΙΚΩΝ
ΜΕΤΑΦΡΑΣΤΙΚΗ ΥΠΗΡΕΣΙΑ
RÉPUBLIQUE HELLÉNIQUE, MINISTÈRE DES AFFAIRES ÉTRANGÈRES
SERVICE DE TRADUCTION
HELLENIC REPUBLIC, MINISTRY OF FOREIGN AFFAIRS
TRANSLATION SERVICE

REPUBLIQUE HELLENIQUE
MINISTERE DES AFFAIRES ETRANGERES
Vu pour legalisation de la signature ci-dessus
du Traducteur du Ministère des Affaires
Etrangères ayant traduit le texte ci-annexé

Athènes le, 14 FEB 2017

PAR DELEGATION DU MINISTRE
Le Directeur p.m.

Pavlidis Ioannis
Admin. Secretary

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia (*Country*): Việt Nam

Giấy tờ, tài liệu này (*This public document*)

2. do Ông (Bà) (*has been signed by*): PAVLIDIS IOANNIS ký
3. với chức danh (*acting in the capacity of*): Viên chức lãnh sự
4. và con dấu của (*bears the seal/stamp of*): Bộ ngoại giao Hy Lạp

Được chứng nhận / hợp pháp hóa lãnh sự (*Certified*)

5. Tại (*at*): Athens 6. Ngày: 15/02/2017
7. Cơ quan cấp (*by*): Đại sứ quán Việt Nam tại Hy Lạp
8. Số (*No*): 370/ CNLS/HPHLS

Ký tên và đóng dấu (*Signature and seal/stamp*)
Tham tán Công sứ

Phạm Hữu Đức

ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ΗΜΕΡΟΜΗΝΙΑ: 25/04/2017
ΑΡ. ΠΡΩΤ.: 53248

ΠΡΟΣ ΚΑΘΕ ΕΝΔΙΑΦΕΡΟΜΕΝΟ / TO WHOM IT MAY BE CONCERN

ΒΕΒΑΙΩΣΗ

Βεβαιώνεται ότι οι εμπορικοί τύποι των ιατροτεχνολογικών προϊόντων που αναφέρονται στην ακόλουθη λίστα καλύπτονται από το υπ' αριθ. 301011039 πιστοποιητικό συμμόρφωσης της εταιρείας **ΓΕΡΟΛΥΜΑΤΟΣ INTERNATIONAL Α.Ε.Β.Ε.** σύμφωνα με τις απαιτήσεις της Οδηγίας 93/42/ΕΟΚ , Παράρτημα V.

We hereby certify that the under mentioned commercial types of the listed medical devices are covered by the certificate of compliance 301011039 of the company GEROLYMATOS INTERNATIONAL S.A. according to the requirements of Directive 93/42/EEC, Annex V.

1. ΡΙΝΙΚΑ ΔΙΑΛΥΜΑΤΑ / NASAL SOLUTIONS

1.1. SINOMARIN 2,3% NOSE CARE CHILDREN-ADULTS (50-100-125 ml)
1.2. SINOMARIN 2,3% E.N.T. (50-200 ml)
1.3. SINOMARIN 2,3% BABIES
1.4. SINOMARIN 2,3% COLD & FLU RELIEF(100 ml)
1.5. SINOMARIN 2,6% (100-125 ml)
1.6. SINOMARIN 3,1% (100-125 ml)
1.7. ISOMARIN 0,9% (100-125 ml)
1.8 SINOMARIN PLUS ALGAE ALLERGY RELIEF NASAL SPRAY (50 & 100 ml)
1.9 SINOMARIN PLUS ALGAE COLD & FLU RELIEF NASAL SPRAY (50 & 100 ml)
1.10 SINOMARIN PLUS ALGAE ENT NASAL SPRAY (125ml)
1.11 SINOMARIN DRY NOSE RELIEF NASAL SPRAY (50 & 100 ml).

Για το ΕΚΑΠΤΥ ΑΕ / For EKAPTY S.A.

Χ. Παπαδάκης, Πρόεδρος & Διευθύνων Σύμβουλος
H. Papadakis, President & Managing Director