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No. 155119

HELLENIC REPUBLIC

MINISTRY OF HEALTH & SOCIAL SOLIDARITY

NATIONAL ORGANIZATION FOR MEDICINES (EOF)

284, Messogion Ave., GR15562 Holargos

website: www.eof.gr

Division of Product Evaluation

Department of Medical Supplies Evaluation

Enquiries: Mrs. M. Perpiraki

Tel. No. 210 6507407 / Fax: 210 6507450

Holargos, 5.4.2011

Ref. No. 14614

To: M. & E. VEZIRIS O.E.

69-71 Paleologou Street

Postal Code 15232 Halandri

CERTIFICATE OF RE-REGISTRATION IN THE REGISTER OF MANUFACTURERS OF MEDICAL DEVICES of Class I

Taking into consideration:

- 1. Joint Ministerial Decision DY8d/130648/30..8.2009 No. В 2198/2.10.2009) (Government Gazette issue "Harmonisation of Hellenic Legislation Directive to 93/42/EEC/14.6.1993 of the Council of the European Union" as currently applicable;
- 2. Your application No. 14614/25.2.2011 for re-registration in the Register of Medical Device Manufacturers and its attached supporting documents;
- Certificate No. 17788/21.6.2006 (expiring on 6.4.2011) on your previous registration with the Register of Medical Device Manufacturers kept by EOF.

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ, ΥΠΟΥΡΓΕΙΟ ΕΞΩΤΕΡΙΚΩΝ ΜΕΤΑΦΡΑΣΤΙΚΉ ΥΠΗΡΕΣΙΑ

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WE CERTIFY

That you are re-registered in the Register of Medical Device Manufacturers kept by EOF, as per the provisions of article 14 of the relevant Joint Ministerial Decision No. DY8d/130648/30.8.2009 (Government Gazette issue No. B/2198/2.10.2009), under the following details:

Manufacturer	M. & E. VEZIRIS O.E.
Address	69-71 Paleologou Street, Postal Code 15232
	Halandri
Phone	210 6820611
Fax	210 6852383

REGISTRATION NUMBER(*)	:	I	404	04	2016
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(*) The Registration Number is comprised of the designation ($I = Class\ I$ or CM=Custom-made device), the Code Number and the Expiration date of your Registration (04/2016)

CLASS I DEVICES

FOLDING WHEELCHAIR WITH DETACHABLE SEAT AND MOVING BACK (BODY UP)

The above product of your company, when they are placed on the market, must bear the CE marking (article 17 of Ministerial Decision DY8d/130648/30.8.2009 (Government Gazette issue No. B/2198/2.10.2009).

<u>In the case of unduly affixing of the CE Mark, article 18 of the above-stated Ministerial Decision shall be applicable.</u>

The Manufacturer, pursuant to Annex VII, paragraph 2, of Ministerial Decision DY8d/130648/30.8.2009 (Government Gazette issue B/2198/2.10.2009), prepares the technical dossier

ΕΛΛΗΝΙΚΉ ΔΗΜΟΚΡΑΤΊΑ, ΥΠΟΥΡΓΕΙΌ ΕΞΩΤΕΡΙΚΩΝ ΜΕΤΑΦΡΑΣΤΙΚΉ ΥΠΗΡΕΣΙΑ

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containing the technical documentation as set out under point 3 of the said Annex. The said dossier, along with the Declaration of Conformity, must be made available to EOF for inspection purposes for a period of five years minimum after the date the last of such products was manufactured.

Your registration with the register of manufacturers of Class I Medical Devices is effected in implementation of article 14 of Ministerial Decision DY8d/130648/30.8.2009 (Government Gazette issue No. B/2198/2.10.2009, on the basis of the Declaration of Conformity submitted by you and it does not constitute any kind of endorsement with respect to the device quality, safety and effectiveness.

Your registration is valid until 06.04.2016 (expiration date of the original certificate of registration/re-registration having a validity of five years).

Two (2) months before the expiration hereof and provided you continue to manufacture the said devices you must proceed with re-registration by submitting the relevant supporting documents to EOF.

Any change to the details contained in this certificate must be notified to EOF by means of submission of a new application for amending and/or supplementing the previous one.

The Director: Dr. AIK. MORAITI

The accuracy hereof is attested by the Head of the EOF General Secretariat Services, Mrs. Despina Kontogianni (Signed-Sealed)

True translation of the attached certified document in Greek.

Athens, 28.12.2011 M. Kontopidou | Translator

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