

HELLENIC REPUBLIC

MINISTRY OF HEALTH AND

SOCIAL SOLIDARITY

NATIONAL ORGANIZATION OF MEDICINES

284 Mesogeion Av, 155 62 Xolargos

www.eof.gr

GR/CA01

Management: Evaluation of products

Department: Evaluation of Sanitary Material

Information: M. Perpiraki

Phone number: 2106507407 / Fax: 2106507450



Xolargos : 27-09-2010

Register Number: 59297

TO: STAVROS AGGELOPOULOS & SIA O.E.

"VAKTRO"

34 ARATOU Str.,26331, Patras

CERTIFICATE OF REGISTRATION

AT MANUFACTURERS' S REGISTER OF IN VITRO DIAGNOSTICS MEDICAL PRODUCTS

Whereas:

1. The Joint Ministerial Decision (JMD) DY8d/oik. 3607/892/OGG issue 1060B/10-8-2001 about "Harmonization of the Hellenic Legislation with the Directive 98/79/ EC of the European Parliament and the October 27, 1998 Council, regarding the in vitro diagnostic medical products"
2. No 62701/27-11-2003 and No 63222/1-12-2003 circulars of National Organization of Medicines
3. Your application with register number 59297/1-9-2010 and the attached to it required supporting documents

WE HEREBY CERTIFY

That you have registered the records of the National Organization of Medicines, according to what article 10 of the JMD DY8d/3607/892/2001 dictates, with below mentioned data:

| | |
|--------------|---|
| MANUFACTURER | BIOLA, LTD |
| ADDRESS | 154 3 rd Cherepkovskaya, 121552 MOSCOW, RUSSIA |
| PHONE NUMBER | +7 495 414-9747 |
| FAX NUMBER | +7 495 414-6748 |
| e-mail | info@biola.ru |

| | |
|---------------|--|
| ASSIGNEE | STAVROS AGGELOPOULOS & SIA O.E. "VAKTRO" |
| ASSIGNEE CODE | GRAR32 |
| ADDRESS | 34 ARATOU Str.,26331, PATRAS, GREECE |
| PHONE NUMBER | +30 2610 223999 |
| FAX NUMBER | +30 2610 223595 |
| e-mail | info@vaktro.gr |

IN VITRO DIAGNOSTIC MEDICAL PRODUCTS

| S/N | PRODUCT NAME | PRODUCT CATEGORY | EDMA CODE | NOM REGISTRATION CODE |
|-----|--------------|--|-------------|-----------------------|
| 1 | SFA-500-2 | IC HARDWARE+ DEDICATED ACCESSORIES Sperm Analyzer | 21.02.10.01 | GR/CA01/GRAR32/O/0001 |

The in vitro Diagnostic Medical Products registration is being made in application of what article 10 of the JMD DY8d/oik. 3607/892/OGG issue 1060B/10-8-2001 dictates.

The manufacturer, in order to apply the CE sign, follows the procedure described in annex III and draws up the required statement of conformity, before these products are put on the market.

The manufacturer is obliged to maintain the statement of conformity and the technical documentation described in annex III, and to provide the National Organization of Medicines with them, in case of control, for a five year period from the last product's manufacture. In case that the manufacturer is not established within the European Union, then, the responsibility of providing, if it is asked, the above mentioned documentation, weighs on his assignee.

The in vitro Diagnostic Medical Products registration is based on the statement of conformity with which you have provided our Service and it is not product quality, safety and effectiveness approval of any kind.

Your registration is valid until 27/09/2015 (expire date of the initial registration certificate with five year validity).

THE MANAGERESS

Dr AIK. MORAITI

(Stamp and Signature)

Faithful translation from Greek
to English language.

Patras, 11/11/2010

The lawyer who did the translation

ΜΑΡΙΑ ΧΡ. ΜΑΚΑΡΙΤΗ
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