GROUP ALKOR BIO

Alkor Bio Company, Ltd.,192148, Zheleznodorozhnii prospect, 40 lit.A, Saint-Petersburg, Russia
Tel.+7-812-677-47-29, +7-812-677-87-79, Fax +7-812-677-47-28, www.alkorbio.ru, www.alkorbiogroup.ru

DECLARATION N°: 2020-01

EC DECLARATION OF CONFORMITY

Manufacturer:	Alkor Bio Company, Ltd., 192148, Zheleznodorozhnii prospect, 40 lit.A Saint-Petersburg, Russia,
European Authorized Representative:	Medimark Europe Sarl , 11 rue Emile Zola – BP 2332 38033 Grenoble Cedex 2 France
Products:	See list in annex
Classification:	Annex III Medical Devices for In Vitro Diagnostic (for professional use)
Conformity Assessment Route:	Annex III

We herewith declare that the products listed in the annex of this document meet to essential requirements of the Directive 98/79/EC of October, 27th 1998 on In Vitro Diagnostic Medical Devices.

Standards applied:	EN ISO 9001, ISO 13485, EN ISO 14971 (ISO 14971), EN 13612, EN 23640, EN 13641, EN 13975, EN ISO 18113-1 (ISO 18113 – 1), EN ISO 18113-2 (ISO 18113 – 2)
QMS Certificate (ISO 13485:2016)	10226924

St. Petersburg

Name of the authorized person
Title

Irina Talynkova
QA Manager

Signature

Digitally signed by Monastîrschii Viorica
Date: 2021.04.20 15:13:36 EEST
Reason: MoldSign Signature
Location: Moldova

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Annex to DECLARATION N°: 2020-01

List of Annex 3 Medical Devices for In Vitro diagnostic for professional use in relation with the above declaration

N	Product name
1	SulfateEIA-DHEA-sulfate
2	SteroidEIA-cortisol
3	SteroidEIA-SHBG
4	SteroidEIA-progesterone
5	SteroidEIA-testosterone
6	SteroidEIA-17-OH-Progesterone
7	EIA-AFP
8	EIA-Ferritin
9	EIA-prolactin
10	PAPP-A
11	GonadotropinEIA-LH
12	GonadotropinEIA-FSH
13	GonadotropinEIA-hCG
14	GonadotropinEIA-free-hCG kit
15	ThyroidEIA-free T3
16	ThyroidEIA-triiodothyronine
17	ThyroidEIA-free T4
18	ThyroidEIA-thyroxin
19	ThyroidEIA-TSH
20	ThyroidEIA-anti-TG
21	ThyroidEIA-anti-TPO
22	ThyroidEIA-TG
23	OncoEIA-CA-125
24	AllergoEIA-total IgE
25	AllergoEIA-specific IgE (including biotinylated allergens)
26	AllergoELISA-specific IgE

Saint-Petersburg, 16 March 2020

Name of the authorized person: Irina Talynkova

Title : QA Manager

Signature: _____

Lloyd's Register

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Dia Lab Services S.R.I.
Via del Babuino 51,
00187 Rome
Italy

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:	LRQ 4009381
Original Approval:	8 October 2015
Current Certificate:	20 March 2019
Certificate Expiry:	19 March 2022

LRQA Notified Body Number 0088

David Dennis

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.

Lloyd's Register

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4009381 SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Dia Lab Services S.R.I.
Via del Babuino 51,
00187 Rome
Italy

Annex II List B Products

Cytomegalovirus IgG
Cytomegalovirus IgG Avidity
Cytomegalovirus IgM Capture
Rubella IgG
Rubella IgG Avidity
Rubella IgM Capture
Toxoplasma IgG
Toxoplasma IgG Avidity
Toxoplasma IgM Capture

Schedule Issue: 01

Date of Schedule Issue: 20 March 2019

LRQA Notified Body Number 0088

David Dunn

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.