

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)  
Annex III

Conformity Assessment Route:  
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, 27<sup>th</sup> 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



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

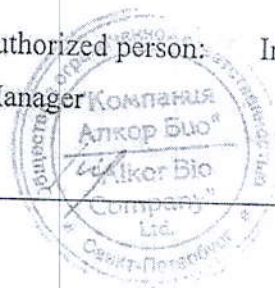
N	Product name
1	SulfateEIA-DHEA-sulfate
2	SteroidEIA-cortisol
3	SteroidEIA-SHBG
4	SteroidEIA-progesterone
5	SteroidEIA-testosterone
6	SteroidEIA-17-OH-Progesterone
7	EIA-AFP
8	EIA-Ferritin
9	EIA-prolactin
10	PAPP-A
11	GonadotropinEIA-LH
12	GonadotropinEIA-FSH
13	GonadotropinEIA-hCG
14	GonadotropinEIA-free-hCG 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: \_\_\_\_\_



## 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.L.**  
**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



Issued by: Lloyd's Register Quality Assurance Limited

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





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**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.L.  
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

Issued by: Lloyd's Register Quality Assurance Limited  
Page 1 of 1

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

# Certificate of Approval

This is to certify that the Management System of:

## Alkor Bio Group

40, Lit. A, Zheleznodorozhnyi Prospekt, St.Petersburg, 192148, Russian Federation

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016  
EN ISO 13485:2016  
BS EN ISO 13485:2016



P.G. Cornelissen - Area Manager North Europe

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 11 November 2019

Expiry date: 10 November 2022

Certificate identity number: 10226924

Original approval(s):

ISO 13485 – 10 November 2010

Approval number(s): ISO 13485 – 0069339

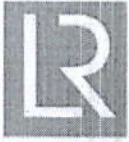
The scope of this approval is applicable to:

Design, development, manufacture, distribution and marketing of reagents, kits of reagents for "in vitro" diagnostics and automated analyzers for "in vitro" diagnostics.



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# Certificate Schedule

Certificate identity number: 10226924

Location	Activities
<p>Alkor Bio Company Ltd 40, Lit. A, Zheleznodorozhniy Prospect, St.Petersburg, 192148, Russian Federation</p>	<p>Design, development, manufacture, distribution and marketing of reagents, kits of reagents for "in vitro" diagnostics and automated analyzers for "in vitro" diagnostics.</p>
<p>VEGA Ltd 40, Lit. A, Zheleznodorozhniy Prospect, St.Petersburg, 192148, Russian Federation</p>	<p>Design, development, manufacture of reagents and kits of reagents for "in vitro" diagnostics.</p>
<p>Alkor Bio Ltd 40, Lit. A, Zheleznodorozhniy Prospect, St.Petersburg, 192148, Russian Federation</p>	<p>Distribution and marketing of reagents and kits of reagents for "in vitro" diagnostics.</p>
<p>Alkor Impex Ltd 40, Lit. A, Zheleznodorozhniy Prospect, St.Petersburg, 192148, Russian Federation</p>	<p>Distribution and marketing of reagents and kits of reagents for "in vitro" diagnostics.</p>



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