

ЗАО «ЭКОлаб» 142530 Московская обл, г.Электрoгoрск, ул.Буденного, д.1
e-mail: sekretar@ekolab.ru, Сайт : www.ekolab.ru
Тел: (49643) 3-1374, 3-2311, факс (49643) 3-3143



ИНН: 5035025076, КПП: 503501001
Банк получателя: ПАО Сбербанк России г. Москва
в Орехово-Зуевском ОСБ № 1556/063
р/с 40702810040310124002
к/с 30101810400000000225
БИК 044525225

21.03.2018

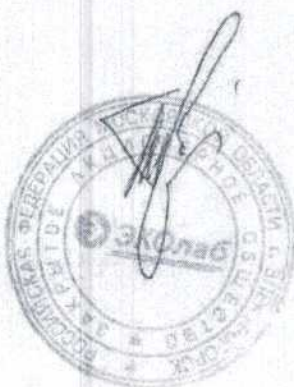
АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

Закрытое акционерное общество «ЭКОлаб» (Россия, 142530, Московская обл., г.Электрoгoрск, ул.Буденного, д.1) настоящим подтверждаем, что "SANMEDICO" SRL (ул. Коробчану 7А, кв. 9, г. Кишинёв, Республика Молдова) является нашим эксклюзивным дистрибьютором в Республике Молдова и осуществляет участие с продукцией ЗАО «ЭКОлаб» в процедурах государственных закупок товаров на территории Республики Молдова, от своего имени ведет переговоры, представляет коммерческие предложения, заключает соответствующие договоры, а также осуществляет поставки указанной продукции на территории Республики Молдова.

Полномочия по настоящему авторизационному письму не могут быть переданы другим лицам.

Настоящее письмо действительно с момента подписания и до 31 декабря 2018г.

Генеральный директор



Борисов В.Ю.





Certificat

Certificate

N° 2007/28641.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:



ЗАО «ЕКОлаб»
ЗАО «ЭКОлаб»



for the following activities:
для следующей области деятельности:

**DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES
FOR IN-VITRO DIAGNOSTICS AND OF FINISHED MEDICINE**

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ
IN-VITRO ДИАГНОСТИКИ И ЛЕКАРСТВЕННЫХ СРЕДСТВ

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 9001 : 2015

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А

This certificate is valid from (начинает действовать)
Данный сертификат действителен с (срок выдачи/дата):

2016-02-21

until (до)

2019-02-21

Managing director of AFNOR Certification
Генеральный директор АФНОР Сертификейшн

F. LEBEUGLE

11, rue Francis de Pressensac - 93371 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 68 68 - F. +33 (0)1 48 17 30 30
545 rue Leprieux 101 197 006 - 478 078 302 805 Buldary - 00359 2277 301



11, rue Francis de Pressensac - 93371 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 68 68 - F. +33 (0)1 48 17 30 30
545 rue Leprieux 101 197 006 - 478 078 302 805 Buldary - 00359 2277 301



Certificat

Certificate

N° 2007/28642.4

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:



ЗАО «ЕКОлаб»
ЗАО «ЭКОлаб»



for the following activities:
для следующей области деятельности:

**DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES
FOR IN-VITRO DIAGNOSTICS.**

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ
IN-VITRO ДИАГНОСТИКИ

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485 : 2003

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А

This certificate is valid from (начинает действовать)
Данный сертификат действителен с (срок выдачи/дата):

2016-02-21

until (до)

2019-02-21

Managing director of AFNOR Certification
Генеральный директор АФНОР Сертификейшн

F. LEBEUGLE

11, rue Francis de Pressensac - 93371 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 68 68 - F. +33 (0)1 48 17 30 30
545 rue Leprieux 101 197 006 - 478 078 302 805 Buldary - 00359 2277 301



11, rue Francis de Pressensac - 93371 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 68 68 - F. +33 (0)1 48 17 30 30
545 rue Leprieux 101 197 006 - 478 078 302 805 Buldary - 00359 2277 301



San Diego July 11th, 2018

We, ACON Laboratories Inc. having a registered office at 10125 Mesa Rim Road. San Diego, CA 92121, USA assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

ACON reserves the right to cancel this authorization at any time with a one month notice. If this is the case, ACON will honor any obligation to supply to our representative SanMedico SRL all the products distribution acquired or in the process of being acquired in Public Price bids and Public Tenders process.

Sincerely,

Jassy Alvarenga

Account Manager, International Sales



ACON Laboratories





Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

Holder of Certificate: Acon Biotech (Hangzhou) Co., Ltd.

No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA



Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
In Vitro Diagnostic Test Kits
and Related Instruments,
Lancet and Lancing Device

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1610619

Valid from: 2016-07-15
Valid until: 2019-07-14



Date, 2016-07-08
Stefan Preiß
Stefan Preiß

Page 1 of 1

TÜV SUD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

DAKKS
Deutsche
Akkreditierungsstelle



Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China 310030

We declare under our sole responsibility that the *in vitro* diagnostic device:

On Call Plus Blood Glucose Monitoring System
On Call Plus Blood Glucose Meter
On Call Plus Blood Glucose Test Strip
On Call Plus Glucose Control Solution

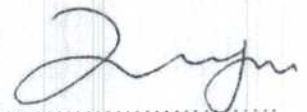
meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

**This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH, Ridlerstraße 65
80339 MÜNCHEN, Germany, notified under
No. 0123 to the EC Commission.**

Authorized Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street,
LONDON W1G 9QR, England, UK

Detailed brand information and first place date, please refer to CE Product List.

Signed this 15 day of 9, 2015
in Hangzhou, China



Junny You
International Regulatory Affairs Manager
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn



Declaration of Conformity

ACON Laboratories, Incorporated
10125 Mesa Rim Road
San Diego, CA 92121 USA

We, the manufacturer, declare under our sole responsibility that
the in vitro diagnostic device:

Mission U500 Urine Analyzer
Mission U500 Urine Analyzer with Barcode Reader
Mission Urine Analyzer Barcode Reader
Mission Printer Paper Rolls (Sticker/Thermal)
Mission U500 Data Transfer Kit

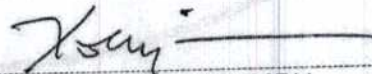
classified as others of the directive 98/79/EC,

meets all the provisions of the directive 98/79/EC on *in vitro*
diagnostic medical devices which apply to it

This self-declaration is according to Annex III
(excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 21st day of March, 2016
in San Diego, CA USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



10125 Mesa Rim Road · San Diego, CA 92121 · USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com



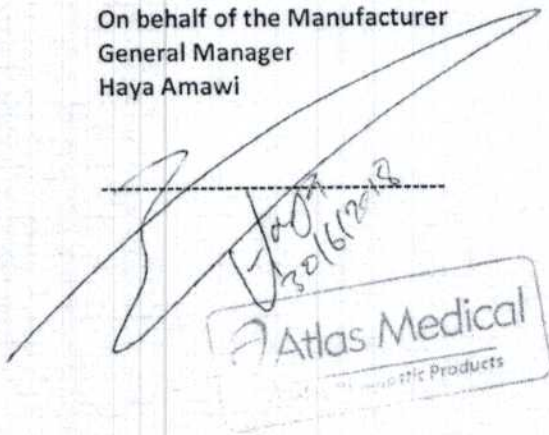
Date: 30/06/2018

STATEMENT

We, **Atlas Medical** having a registered office at William James House, Cowley Road, Cambridge, CB4 0WX, UK assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

On behalf of the Manufacturer
General Manager
Haya Amawi



Handwritten signature of Haya Amawi and a rectangular stamp. The stamp contains the Atlas Medical logo and the text "Atlas Medical" and "Medical Products".

Head Office William James House, Cowley Rd, Cambridge, CB4 0WX, United Kingdom.

Tel: +44 (0) 1223 858910, Fax: +44 (0) 1223 858524

Middle East Site : King Abdullah the Second Industrial Estate, Street 19, Sahab Free Zone Area, P.O. Box: 204, Amman 11121, Jordan





Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

Atlas Medical

King Abdullah II Industrial Estate, Street No. 19, Sahab Free Zone Area, Amman, 11512, Jordan

has been approved by LRQA to the following standards:

ISO 13485:2003

Basem Obaid - Area Operations Manager

Issued By: Lloyd's Register EMEA

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

Current Issue Date: 23 March 2018
Expiry Date: 31 March 2019
Certificate Issue Number: 10067833

Original Approvals:
ISO 13485 28 February 2009

Approval Certificate Number: ISO 13485 – 0046833

The scope of this approval is applicable to:
ISO 13485:2003
Design Manufacturing and Supply of Medical
Diagnostic Reagents and Kits



001





CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,
Atlas Medical
 Head office: William James House, Cowley Road, Cambridge, CB4 0WX, UK
 Tel: +44 1223 858 910
 Fax: +44 1223 858 524
 Email: info@atlas-site.co.uk

Middle East Site: Sahab Free Zone Area, P. O. Box 212555, Amman, Jordan.
 Tel.: +962 6 4026468
 Fax: +962 6 4022588
 Email: info@atlas-medical.com

Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (Annex) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2003) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2, -4:2011, EN ISO 15223:2012, EN ISO 13532:2002, EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002).

And
 intended for In-Vitro Professional use only.

Manufacturer
Atlas Medical
 William James House, Cowley Rd.,
 Cambridge, CB4 0WX, UK

Atlas Medical	Issue date December 2011	Date of review 21st of March, 2018	Management approval 	MRXD010F.10 08.02.2011
---------------	-----------------------------	---------------------------------------	-------------------------	---------------------------

Catalogue No	Description	Description
8.00.00	CRP latex Kits	Calcium Chloride
8.00.01	CRP latex Kits with buffer	Fibrinogen Reagent
8.00.02	ASO latex Kits	Hemoglobin Reagents
8.00.03	ASO latex Kits with buffer	Drabkins Reagent, 40x
8.00.04	RF Latex Kits	Hemoglobin Standard, 15g/dl
8.00.05	RF Latex Kits with buffer	Sickle Cell Kits
8.00.07	hCG Latex Kits	Sickle Cell positive & negative control set
8.00.08	IM (Horse Stroma) Latex Kits	Urine Reagent Strips
8.00.11	SLE Latex Kits	URS 1 Parameter: Glucose
8.00.12	Staphylococcus Latex Kits	URS 1 Parameter: Protein
8.00.13	Streptococcus Latex Kits	URS 1 Parameter: Ketone
8.00.15	E-Coil Latex Kits	URS 2 Parameters: Glucose, Ketone
8.00.16	Rota Virus Latex Kits	URS 2 Parameters: Glucose, Protein
8.00.17	D-Dimer Latex kits	URS 2 Parameters: Urobilinogen, Bilirubin (Liver Function Test)
8.00.21	Waaler rose Latex Kits	URS 3 Parameters: Protein, pH, Glucose
Febrile Antigen Kits		
8.01.00	Brucella rose Bengal	URS 3 Parameters: Glucose, Protein, Ketone
8.01.01	Salmonella OA Reagent	URS 9 Parameters: Nitrite, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.02	Salmonella OB Reagent	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.03	Salmonella OC Reagent	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.04	Salmonella OD Reagent	URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.01.05	Salmonella HA Reagent	URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.01.06	Salmonella HB Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.07	Salmonella HC Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.08	Salmonella HD Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.10	Brucella Abortus Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.11	Brucella Melitensis Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.12	Proteus OX2 Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.13	Proteus OX19 Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.14	Proteus OXK Reagent	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.15	Brucella Antigen Kits	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.16	Salmonella Antigen Sets	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.17	Febrile Antigen Set (10 Antigens)	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.17	Febrile Antigen Set (10 Antigens) With controls	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with controls	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.19	Febrile Antigen Positive Control	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.01.20	Febrile Antigen Negative Control	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
Coagulation Reagents		
8.02.40	PT Calcium Rabbit Brain	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.41	Thromboplastin, liquid	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.60	APTT (PTT) Micronised Silica Platelet Substitute, Liquid	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.61	Normal Coagulation Control	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.61	Abnormal Coagulation Control	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.44	PT Kit	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.02.45	APTT (PTT) Kit	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
Fertility Rapid Tests		
8.04.00	hCG Test Cassette, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.01	hCG Test Cassette, Urine/Serum	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.04	hCG Test Strip, 5.0mm, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.05	hCG Test Strip, 3.5mm, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.06	hCG Test Strip, 2.5mm, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.10	hCG Test Strip, 5.0mm, Urine/Serum	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.12	hCG Test Strip, 2.5mm, Urine/Serum	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.88	hCG Test Strip, 3.5 mm, Urine/Serum	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.90	hCG Test Strip, 2.5 mm, Urine/Serum	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.14	LH Test Cassette, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.15	LH Test Strip, 3.5mm, Urine	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.04.20	Haplori Antibody Test Cassette, Whole Blood/Serum (Phospor)	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose

