



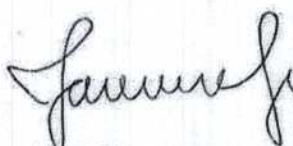
San Diego July 11th, 2018

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

ACON LABORATORIES, INC. : 10125 MESA RIM ROAD SAN DIEGO, CA 92121 : T 858.875.8000 F 858.875.8098 aconlabs.com





Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Manufacturer:

ACON Laboratories, Inc.

10125 Mesa Rim Road
San Diego CA 92121
USA



EC-Representative:

Medical Device Safety Service GmbH

Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies):

In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.:

SH17743EXT01

Valid from:
Valid until:

2017-09-13
2022-09-12



Date, 2017-08-30

S. Pfeiß
Stefan Pfeiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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



Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Model(s):

For Detail Models see attachment

Facility(ies):

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA
AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA



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

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

For the product(s)/product category (ies):

- On Call Plus Blood Glucose Monitoring System,
On Call Plus Blood Glucose Test Strips,
On Call EZ II Blood Glucose Monitoring System,
On Call Redi Blood Glucose Monitoring System,
On Call Redi II Blood Glucose Test Strips,
On Call Advanced Blood Glucose Monitoring System,
On Call Advanced Blood Glucose Test Strips,
On Call Platinum Blood Glucose Monitoring System,
On Call Platinum Blood Glucose Test Strips,
On Call Chosen Blood Glucose Monitoring System,
On Call Chosen Blood Glucose Test Strips,
On Call Vivid Blood Glucose Monitoring System (OGM-101),
On Call Vivid Blood Glucose Test Strips (OGS-101),
On Call Vivid Pal Blood Glucose Monitoring System (OGM-102),
On Call Sharp Blood Glucose Monitoring System (OGM-121),
On Call Sharp Blood Glucose Test Strips (OGS-121)
On Call Plus II Blood Glucose Monitoring System (OGM-171),
On Call Plus II Blood Glucose Test Strips (OGS-171),
On Call Extra Blood Glucose Monitoring System (OGM-191),
On Call Extra Blood Glucose Test Strips (OGS-191),
On Call GK Dual Blood Glucose & Ketone Monitoring System (OGM-161),
D-ONE Blood Ketone Test Strips (OGS-161),
D-ONE Blood Glucose Monitoring System,
D-ONE Blood Glucose Test Strips,
Urinalysis Reagent Strips (Urine),
UTI Urinary Tract Infection Test Strips,
Toxoplasma IgG EIA Test Kit,
Toxoplasma IgM EIA Test Kit,
Rubella IgG EIA Test Kit,
Rubella IgM EIA Test Kit,
CMV IgG EIA Test Kit,
CMV IgM EIA Test Kit,

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

- Total PSA EIA Test Kit.
PT Coagulation Monitoring System (CCM-121),
PT Coagulation Test Strips (CCS-121),
Cholesterol Monitoring System (CCM-111),
CHOL Total Cholesterol Test Devices (CCS-111),
TRIG Triglycerides Test Devices (CCS-112),
HDL High Density Lipoprotein Test Devices (CCS-113),
3-1 Lipid Panel Test Devices (CCS-114),
Cholesterol CTRL Control Devices,
Cholesterol Monitoring System (CCM-101),
CHOL Total Cholesterol Test Strips (CCS-101),
PT/INR Monitoring System (CCM-151),
PT/INR Test Strips (CCS-151),
Hemoglobin Testing System (CCM-141),
Hemoglobin Test Strips (CCS-141),
hCG Pregnancy Rapid Test Cassette (Urine),
Pregnancy Rapid Test Midstream

Munich, MHS-CRT, 2017-08-30

J. Purvis

Stefan Preiß

Certification Medical Technology





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



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DAKkS

 Deutsche
 Akkreditierungsstelle
 D ZM 1132

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



ЗАО «ЭКОлаб» 142530 Московская обл, г.Электрoгoрск, ул.Буденнoгo, 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.Буденнoгo, 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 «EKOlab»
ЗАО «ЭКОлаб»



for the following activities:
для следующих областей 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, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А**

This certificate is valid from (valid from/validity date)
Данный сертификат действителен с (срок действия/дата):

2016-02-21

until
до

2019-02-21

Managing director of AFNOR Certification
Генеральный директор AFNOR Certification

F. LEBEUQUE

This certificate is valid from (valid from/validity date) and is developed on the following locations:
Данный сертификат действителен с (срок действия/дата) и действует на следующих площадках:

afnor
CERTIFICATION

11, rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 48 17 90 00
SAS au capital de 15 167 000 € - 478 578 602 RCS Boulogne - www.afnor.org



Certificat

Certificate

N° 2007/28642.4

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



ЗАО «EKOlab»
ЗАО «ЭКОлаб»



for the following activities:
для следующих областей 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, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А**

This certificate is valid from (valid from/validity date)
Данный сертификат действителен с (срок действия/дата):

2016-02-21

until
до

2019-02-21

Managing director of AFNOR Certification
Генеральный директор AFNOR Certification

F. LEBEUQUE

This certificate is valid from (valid from/validity date) and is developed on the following locations:
Данный сертификат действителен с (срок действия/дата) и действует на следующих площадках:



11, rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 48 17 90 00
SAS au capital de 15 167 000 € - 478 578 602 RCS Boulogne - www.afnor.org

STATEMENT

We, "Technology-Standard" Ltd. having a registered office at 116/95, Kalinin Prospekt, Barnaul, 656037, Russia, 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/EC.

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

"Tecnology-Standart" Ltd
116/95 Kalinin Prospekt
City of Barnaul, 656037, Russia

SRL SANMEDICO
A. Corobceanu street 7A, apt. 9,
Chişinău MD-2012, Moldova

Date: 01.12.2017

Director: Mr. A. B.

Signature: _____



ЗАЯВЛЕНИЕ

Мы, ООО «Технология-Стандарт», имеющее зарегистрированный офис по адресу 116/95, проспект Калинина, г. Барнаул, 656037, Россия, поручают SRL SANMEDICO, имеющую зарегистрированный офис на улице А.Коробчану 7А, кв. 9, Кишинёв MD-2012, Молдова, быть в качестве уполномоченного представителя в соответствии с условиями директивы 98/79/EC.

Мы заявляем, что упомянутая выше компания имеет право регистрировать, уведомлять, обновлять или возобновлять регистрацию медицинских изделий на территории Республики Молдова.

ООО Фирма «Технология-Стандарт»
656037 Россия г.Барнаул,
пр-кт Калинина 116/95

SRL SANMEDICO,
г. Кишинёв MD-2012, Молдова
ул. А.Коробчану 7А, кв. 9

Дата: 01.12.2017

Директор: А. Б.

Подпись: _____





3EC[®]
International

SNAS
Reg. No. 305/Q-054

CERTIFICATE

*This certifies that the Quality management system for medical devices
of company*

«Technology-Standard» LTD

116/95, Kalinin Prospekt, City of Barnaul, 656037
RUSSIA

*has been assessed by 3EC International
and found to be in conformance with the following standard:*

EN ISO 13485:2012
(ISO 13485:2003 + Cor 1:2009)

for the following scope:

**DEVELOPMENT, PRODUCTION AND SALES OF DIAGNOSTIC KITS AND
REAGENTS FOR IN VITRO DIAGNOSTICS OF HEMOSTASIS SYSTEM**

Certificate No.: M-0379/16

Date of issuance: August 5th, 2016

Original date of approval: August 5th, 2016

This certificate is valid from August 5th, 2016 to March 1st, 2019 on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18 821 05 Bratislava, Slovak Republic



Dr. Katarína Srdosová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SRM (Slovak Republic Metrology) number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management system for medical devices.





Declaration of Conformity	Document ref.: DoC2015 vs. 02 Page: 1 of 6
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DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): "Technology-Standard" Ltd
Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia
and
2) European authorized representative: CEpartner4U BV,
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) (name, type or model/batch number, etc.):
- Kits and reagents for in vitro diagnostics of haemostasis system
see appendix

4) The product(s) described above is in conformity with:	
<u>Title</u>	<u>Document No.</u>
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):
Conformity assessment procedure for CE marking: In vitro Diagnostic Medical Device Directive,
Annex III
Registration nr.: NL-CA002-2015-34420



Barnaul, Russia; 2015-03-17 Andrey Momot, Director "Technology-Standard" Ltd
(Place & date of issue (YYYY-mm-dd)) (name, function and signature of manufacturer)



Declaration of Conformity	Document ref.: DoC2015 vs. 02 Page: 2 of 6
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Appendix

Date: 2015-02-09

List of devices.

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Techplasin-tests» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140	Low	13 02 01 01/ 30539	09.02.2015
«SFM/C-test» The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma	081, 007	Low	13 02 03 03/ 43421	09.02.2015
«APTT-tests» The kit of reagents for the determination of activated partial thromboplastin time	152, 001	Low	13 02 01 02/ 32392	09.02.2015
«Tech-Fibrinogen-tests» The kit of reagents for the determination of fibrinogen concentration in blood plasma	324, 094, 225	Low	13 02 02 01/ 30541	09.02.2015
«ChromoTech-Plasminogen» The kit of reagents for the determination of plasminogen concentration in blood plasma	092	Low	13 02 05 05/ 30578	09.02.2015

¹ See EDMS codes: <http://www.edma-ivd.be/> (products classification)/Preference GMDN code

