

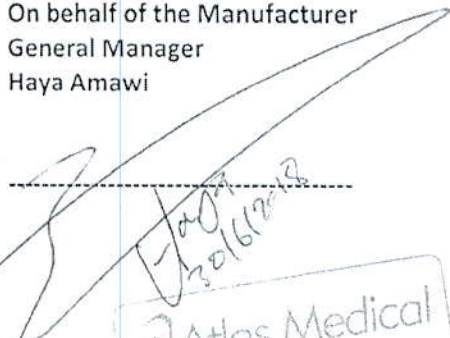
Date: 30/06/2018

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


30/6/2018


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: 209 Amman 11512, Jordan



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 I) 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.,

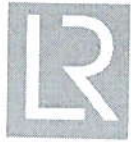
Cambridge, CB4 0WX, UK

Atlas Medical	Issue date	Date of review	Management approval	MRXDD10F.10
	December, 2011	21st of March, 2018		08.02.2011

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

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





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:

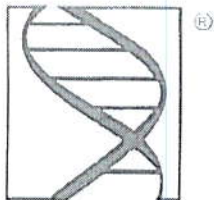
ISO 13485:2003

Design Manufacturing and Supply of Medical
Diagnostic Reagents and Kits



001





SYNTESYS



Cert. N.7111/1



Cert. N.6574/1



SYNTESYS S.A.S. DI RINALDO R. & C.

VIA G. GALILEI, 10/3
35037 Z.I. SELVE DI TEOLO (PD)
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
COD.FISCALE P.IVA N.REG.IMP. PADOVA 03573950288
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

AUTHORIZATION LETTER

We, **Syntesys S.A.S.** having a registered office at Via G. Galilei 10/3, 35037 Selve di Teolo - PD - Italy, assign **Sanmedico SRL** having a registered office at A.Corobceanu str., apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with the conditions of directive 98/79/CE and 93/42/CE.

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.

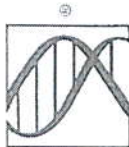
Teolo, 02.01.2018

 **SYNTESYS S.A.S.**
DI RINALDO R. & C.
Via G. GALILEI 10/3
Z.I. SELVE 35037 TEOLO (PD) - CF/P.IVA 03573950288
TEL. 03573903866 FAX 03573903867

Rinaldo Ruggero
CEO and Legal Representative
SYNTESYS S.A.S.



Illegible signature



SYNTESSYS



SYNTESSYS S.A.S. DIRINALDO R & C
VIA G. GALILEI 10/3
35037 ZI. SELVE DI TEOLO PD.
TEL. +39 049 9903666 RA. FAX +39 049 9903667
COD. FISCALE P.IVA N. REG. IMP. PADOVA 03573950288
E-MAIL: INFO@SYNTESSYS.IT - WEB: WWW.SYNTESSYS.IT

DICHIARAZIONE DI CONFORMITA'
Conformity declaration



Il sottoscritto, Rinaldo Ruggiero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggiero legal representative of the company:

produttore/manufacturier

SYNTESSYS S.a.s. di Rinaldo Ruggiero & C.

Indirizzo/address

Via G. Galilei, 10/3 35037 Zona Industriale SELVE DI TEOLO (PADOVA) ITALY

o rappresentante il mandatario autorizzato entro la Unione Europea or representing the authorized mandatary within the European Community

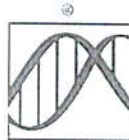
Mandatario autorizzato/authorized mandatary

Indirizzo/address

Dichiara sotto la propria responsabilità che il prodotto/declares under his own responsibility that the product:

Denominazione degli articoli products/description of Manufacturer	Contenitori per urina, contenitori per feci, contenitori universali, Pipette Pasteur, Piastre di Petri, Anse Sterili per batteriologia, Aste a "L", Puntali Eppendorf gialli e blu, cuvette per spettrofotometro, tazzine per campionamento siero, bachette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provetta diam. 12 mm e 16mm, provette con granuli ed acceleratore, provette sottovuoto per prelievo, Sistema SEDIPLAST, Microprovette, Portavetrini, Vetrini precolorati, Portaprovette, supporti per microprovette, bottiglie per raccolta urina.
	Urine container, faeces container, universal container, Pasteur pipette, Petri dishes, Sterile loops, Sterile loops open "L", Eppendorf tips yellow and blue, cuvettes for spectrophotometer, samples cups, Rod to detach clot, disposable forceps, Disposable plastic tubes, winged stoppers for tubes diam. 12mm and 16mm, Test tube with granules and clot activator, vacuum test tube, SEDIPLAST system, micro test tubes, Slides Mailer, "TESTSIMPLETS" slide, rack for test tubes, rack for micro test tubes, Bottles for urine collection.

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABILE LABWARE



SYNTESSYS

Materiale/Material

Polipropilene, Polistirolo, Polietilene e
Polimetilmetacrilato

Polypropylene, Polystyrene, Polyethylene and
Polymethylmetacrylate

È conforme alle disposizioni della direttiva "89/79/CE" concernente i dispositivi medici diagnostici in vitro e recepita in Italia con D.L. del 06/09/2000 n° 332 allegato I (requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della sopra citata direttiva / It meets the CE Directive 98/79 CE about in vitro diagnostic device specifications established by the Italian law n. 392, dated 6th September 2000. The device is made according to the specifications of the III attached of the above-mentioned directive.

Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi la richiede/declares that all technical documents attached to this conformity statement are filed in our company and can be consulted by any authorized body on demand.

Data 07/01/2016
Issued on January 7th 2016

SYNTESSYS S.a.s.
Il legale rappresentante
Rinaldo Ruggiero



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABILE LABWARE

R. Ruggiero



CERTIFICATE





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

SYNTESYS S.a.s. di Rinaldo Ruggero e C.

Via G. Galilei, 10/3 - Zona Industriale - I-35037 Selve di Teolo (PD)

has implemented and maintains a

Quality Management System

for the following scope:

Trading of products for laboratory analysis. Design, manufacturing and sale of products for laboratory analysis and sanitary products. Sale agency of instruments, reagents and consumable products for laboratory diagnostic.

which fulfils the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: 2018-06-04

First issued on: 2014-06-21

Expires on: 2019-06-04

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration Number: IT-93779



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI
NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc



* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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. Iomor

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. Iomor

Подпись: _____



Corobceanu

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: ESPOORLAAN 13, 3951DB MAARN, THE NETHERLANDS;
(on product labels printed as:
CEpartner4U, ESPOORLAAN 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:

Title	Document No.
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)

Appendix

Date: 2015-02-09

List of devices.

Device name	Type/model/ref number	Risk class	Code:EDMS/GMDN	First date of CE-compliance
«Techplastin-test» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140	Low	13 02 01 01/ 30539	09.02.2015
«SFMС-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-test» 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-test» 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

* See EDMS codes: <http://www.edma-ivd.be/> (products classification)



Il Corrucci



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 13485:2016

for the following scope:

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

Certificate No.: M-0379/18

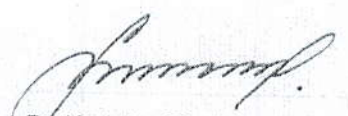
Date of issuance: July 26th, 2018

Original date of approval: August 5th, 2016

This certificate is valid from July 26th, 2018 to August 4th, 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.

This certificate fully supersedes previous certificate No. M-0379/16 issued on August 5th, 2016.

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


Dr. Katarina Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.



Al Goreen

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

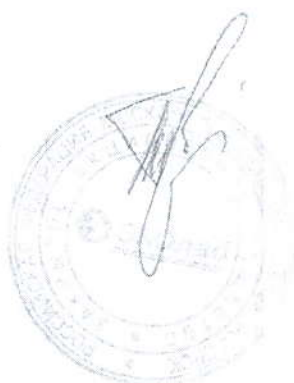
АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

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.





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



for the following activities:
 для проведения следующих мероприятий:

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:

ISO 9001 : 2015

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

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

For Certified up to 15 years: 1 year, 100% only.
 2 years, 90% only. 3 years, 80% only. 4 years, 70% only.
 5 years, 60% only. 6 years, 50% only. 7 years, 40% only.
 8 years, 30% only. 9 years, 20% only. 10 years, 10% only.
 11 years, 0% only. 12 years, 0% only. 13 years, 0% only.
 14 years, 0% only. 15 years, 0% only.

2016-02-21

10

2019-02-21

Managing director of AFNOR Certification
FORNELLANO D'ALBA - AFRICA

F. LEBEUGLE



© 1997 Blackwell Science Ltd, *Journal of Internal Medicine* 241: 395–401

1 rue des amis de Piepiessens - 53111 La Pierre-Saint-Denis France - T +33 (0)3 43 47 43 43 - F +33 (0)3 43 47 43 43
SAS de capital de 14 434 000 € - 429 016 092 RCS Nanterre



N° 2007/28642.4

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



for the following activities:

**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: стандартная.

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

The course is valid from 1 year to 10 days.

[illegible]

2016-02-21

unit=

2019-02-21

Managing director of AFNOR Certification
Président du bureau AFNOR Certification

F. LEBEUGLE



17 rue FROUDE DE MONTMORÉ 91271 LE PÉLAGY SAINT-GENIS-LES-VALS France - T. 03 10 11 41 52 20 00 F. - 03 10 11 40 17
e-mail: edf@le-pelagysaint-genis.com www.le-pelagysaint-genis.com



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

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

Stefan Fiedl

S. Fiedl



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

Page 1 of 4

TÜV SÜD Product Service GmbH Zertifizierstelle Rüdigerstraße 65 80539 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

Page 2 of 4



TÜV SÜD Product Service GmbH Zertifizierstelle Rüdigerstraße 65 80539 München Germany

Stefan Fiedl

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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



Page 1 of 1

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





LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 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.

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President



Alcoru

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No:

FM 574919

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-10-20

Effective Date: 2017-10-20

Latest Revision Date: 2018-11-21

Expiry Date: 2020-10-19



Page: 1 of 1

...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory.
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.





LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0001
Fax: 408-855-0003
E-mail: info@lumiquick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name		Model/number
H. Pylori Ab/Ag Test Devices		
QuickProfile H. Pylori Antigen Test Card		71020
QuickProfile H. Pylori Antibody Test Card Whole Blood		71024
QuickProfile H. Pylori Antibody Test Card-Serum		71046
QuickProfile H. Pylori Antigen Test Strip		71061
QuickProfile H. Pylori Antibody Serum Test Strip		71064
QuickProfile H. Pylori Antibody WB Test Strip		71086

MANUFACTURER		
Name of company	Address	Representative
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager

SIGNATURE:

DATE: 28/04/2017

EC_Declaration_Letter_Emergo_E2R0_NewAddress

