



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





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

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

## Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Cardiac Marker Test Devices		
QuickProfile Troponin I Serum Test Card	75001	
QuickProfile Troponin I Whole Blood Test Card	75002	
QuickProfile Cardiac Panel Serum Test Card	75003	
QuickProfile Cardiac Panel Whole Blood Test Card	75004	
QuickProfile Myoglobin Serum Test card	75005	
QuickProfile Myoglobin Whole Blood Test Card	75006	
QuickProfile CK-MB Serum Test Card	75007	
QuickProfile CK-MB Whole Blood Test Card	75008	
QuickProfile Troponin I Strip	75009	
QuickProfile CK-MB Strip	75010	
QuickProfile Myoglobin Strip	75011	
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 europa@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



# bsi.



By Royal Charter

## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 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:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2011-10-20

Latest Revision Date: 2017-10-09

Effective Date: 2017-10-20

Expiry Date: 2019-02-28

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](http://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.



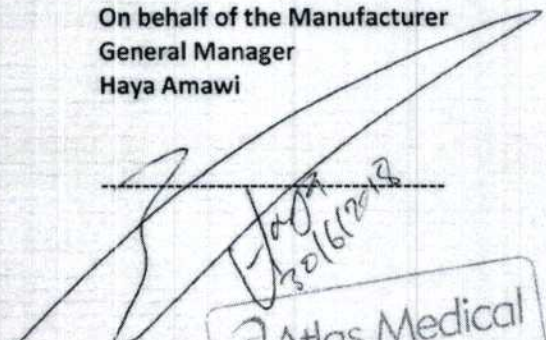
Date: 30/06/2018

## 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



30/06/2018

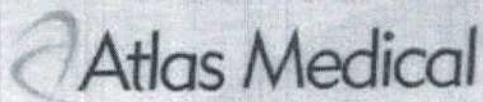


Atlas Medical  
Medical Products

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 11512, Jordan





Declaration Ref No: DC11-0011

CE Declaration of Conformity

We,  
Atlas Medical

Head office: William James House, Cowley Road, Cambridge, CB0 4WX, UK  
Tel: +910 858 1223 44  
Fax: +524 858 1223 44  
Email: [info@atlas-site.co.uk](mailto:info@atlas-site.co.uk)

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

Declare our responsibility that the following product:

RPR Carbon Antigen

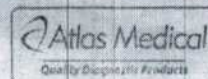
Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003) supported by Lloyd's certificate and complies with the essential requirements of

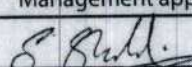
In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex I  
And  
EN 18113-1, -2 :2011, EN ISO 15223:2012  
EN ISO 14971:2012, EN ISO 13640:2002, ISO 2859/1:1999,  
EN ISO 13612:2002, EN ISO 13641:2002

And  
Intended for In-Vitro Professional use only.

This Declaration includes the batches produced beyond this day according to the product Lot Log.

Manufacturer  
Atlas Medical  
William James House, Cowley Rd.  
Cambridge, CB0 4WX, UK



Atlas Medical	First issue date	Date of review	Management approval
	August-2003	06.11.2016	



# Certificate of Approval

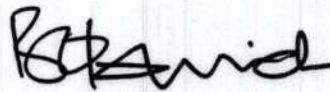
This is to certify that the Management System of:

## 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





San Diego July 11<sup>th</sup>, 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



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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

**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



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:** 2017-09-13  
**Valid until:** 2022-09-12



*S. Preiß*  
 Stefan Preiß

**Date,** 2017-08-30

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

Page 1 of 4



AI / 94.11

AI / 94.11







Product Service

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),
- On Call 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,

ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CEPTNΦNKAT ◆



Product Service

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

*S. F. F. F.*

Stefan Preis  
Certification Medical Technology



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CEPTNΦNKAT ◆





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



*Stefan Preiß*

**Date,** 2016-07-08

Stefan Preiß

Page 1 of 1

DAKKS

Deutsche  
Akkreditierungsstelle  
D ZM-11323-01-00

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



## 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: \_\_\_\_\_





Declaration of Conformity

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

- 1) **Manufacturer** (Name, department): "Technology-Standard" Ltd  
Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia  
and
- 2) **European authorized representative**: CPartner4U BV,  
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;  
CPartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cpartner4u.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:**

<b>Title</b>	<b>Document No.</b>
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 form: Standard ISO/IEC 17050-1:2010

vs. 2011-X



Declaration of Conformity

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


Date: 2015-02-09

List of devices:

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Techplastin-tests» 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-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

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



	Declaration of Conformity	Document ref.: DoC2015 vs. 02
		Page: 3 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«ChromoTech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Plasma-control» The kit of control blood plasma for the study of haemostasis	400	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII-test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-EI-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015


	Declaration of Conformity	Document ref.: DoC2015 vs. 02
		Page: 4 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	012	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» «Techplaslin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	013  144	Low  Low	13 02 50 02/ 32394  13 02 01 01/ 30539	09.02.2015  09.02.2015
«Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of Xlla-kinogenase-dependent spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015



	Declaration of Conformity	Document ref.: DoC2015 vs. 02
		Page: 5 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«MultiTech-Fibrinogen» The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers	711, 712	Low	13 02 02 01/ 30541	09.02.2015
«Fibrinogen-Calibrator» The kit of calibrators for the determination of fibrinogen concentration	714	Low	13 02 50 02 / 39413	09.02.2015
«ADP» The kit of reagents for the determination of ADP-aggregation of platelets	030	Low	13 02 04 01/ 30569	09.02.2015
Ristomycin The kit of reagents for the determination of ristomycin-aggregation of platelets	197	Low	13 02 04 01/ 30569	09.02.2015
«Collagen» The kit of reagents for the determination of collagen-aggregation of platelets	095	Low	13 02 04 01/ 30569	09.02.2015
«Adrenaline» The kit of reagents for the determination of adrenaline-aggregation of platelets	031	Low	13 02 04 01/ 30569	09.02.2015

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

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Aggrescreen-test» The kit of reagents for the express assessment of platelet haemostasis	010	Low	13 02 04 01/ 30569	09.02.2015
«Human platelets»	132	Low	13 02 04 01/ 32409	09.02.2015
«Sodium citrate» A reagent for the stabilization of blood in the study of haemostasis	028	Low	13 02 80 02/ 0	09.02.2015





**3EC**<sup>®</sup>  
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**

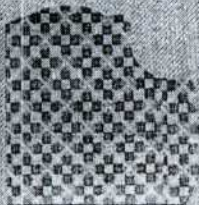
Certificate No.: M-0379/16

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 SNAS (No. 305/Q-054) for registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.





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

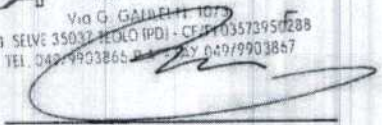
## AUTHORIZATION LETTER

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) - CE.FP.03573950288  
TEL. 049/9903866 R.A. FAX 049/9903867

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







SYNTESSYS



10/09/2008  
C.N. 11/07/08



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**DICHIARAZIONE DI CONFORMITA'**  
*Conformity declaration*



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

produttore/manufacturere

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 mandatory within the European Community

Mandatario autorizzato/authorized mandatory

indirizzo/address

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

Denominazione degli  
articoli  
prodotti/Description of  
Manufacturer

Contenitori per urina, contenitori per feci,  
contenitori universali, pipette Pasteur, piastrine di  
Petri, Anse Sterili per batteriologia, Aste a "L",  
Puntali Eppendorf gialli e blu, cuvette per  
spettrofotometro, tazzina per campionamento siero,  
bacchette per distacco ad estrazione del coagulo,  
pinzette in polistirolo monouso, provette monouso in  
plastica, tappi alettati per provette diam. 12 mm e  
16mm, provette con granuli ad acceleratore, provetta  
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 & 16mm, Test tube with granules and clot  
activator, vacuum test tube, SEDIPLAST system,  
micro test tubes, Slides Mailer, "TESTSIMPLETE" slide,  
Bottles for urine collection.

Materiale/Material

Polipropilene, Polistirolo, Polietilene e  
Polimetilmetacrilato

Polypropylene, Polystyrene, Polyethylene and  
Polymethylmetacrylate

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici  
diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 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. 332, dated 8th 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



®



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:

## ISO 9001:2015

Issued on: **2018-06-04**  
First issued on: **2013-06-05**  
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-83562**



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

**IQNet Partners\*:**

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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**

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**Registration Number: IT-93779**



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

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NYCE-SIGE Mexico PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
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