Atlas Medical

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

Atlas Medical
Diagnostic 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.

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

UKAS MANAGEMENT SYSTEMS
001

Atlas Medical

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

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

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
Quality Diagnostic Products

Atlas Medical	First issue date	Date of review	Management approval	MRXDO10F
	Augsut-2003	06.11.2016		08.02.2011

REPUBLICA MOLDOVA, mun. CHIȘINĂU
CENTRU CONTRACTE ȘI FACTURI
"SANMEDICO"
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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, California 95054 USA
Tel: 1-408-855-0061 info@lumiquick.com
Fax: 1-408-855-0063 www.lumiquick.com

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

...making excellence a habit.™

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATE CU RASPUNDERE LIMITATA

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.I. 03573950288
TEL. 049 9903866 R.A. - FAX 049/9903867

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

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATE CU RĂSPUNDERE LIMITATĂ

SYNTESYS

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

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

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

produttore/*manufacturer*

SYNTESYS S.a.s. di Rinaldo Ruggero & 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 responsability that the product:*

Denominazione degli articoli prodotti/*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 blue, cuvette per spettrofotometro, tazzine per campionamento siero, bacchette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi alettati per provette 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 urine. *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,"TESTSIMPLETS" slides rack for test tubes, rack for micro test tubes, Bottles for urine collection.*

SYNTESYS

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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

Materiale/*Material*	Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato *Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate*

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 1 (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 diagnotic 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 statment are filed in our company and can be consulted by any authorized body on demand.*

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

SYNTESYS S.a.s.
Il legale rappresentante
Rinaldo Ruggero

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
1003600081564
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE

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IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n. / *CERTIFICATE No.* **6574/1**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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

UNITA' OPERATIVE
OPERATIVE UNITS

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

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2008

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

EA: 29 - 14

Commercializzazione di prodotti per analisi di laboratorio. Progettazione, produzione e vendita di prodotti per analisi di laboratorio e articoli sanitari. Agenzia di vendita di strumentazione, reagenti e materiali di consumo per la diagnostica di laboratorio.

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.

Riferirsi al Manuale della Qualità per l'applicabilità dei requisiti della norma di riferimento.
Refer to Quality Manual for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del regolamento per la certificazione dei sistemi di gestione per la qualità delle aziende.
The use and the validity of this certificate shall satisfy the requirements of the rules for the certification of company quality management systems.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
05/06/2013	05/06/2016	14/09/2018

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

CISQ is the Italian Federation of management system Certification Bodies.

ACCREDIA

SGQ N° 004 A
SGA N° 005 D
SCR N° 006 F
PRS N° 082 C
SSI N° 008 G
PRD N° 004 B
ISP N° 046 E
SGE N° 015 H

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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ICIM

www.icim.it

CERTIFICATO n. / *CERTIFICATE No.* **7111/1**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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

UNITA' OPERATIVE
OPERATIVE UNITS

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

E' CONFORME ALLA NORMA
IS IN COMPLIANCE WITH THE STANDARD

UNI CEI EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA'
FOR THE FOLLOWING ACTIVITIES

EA: 29 – 14

Commercializzazione di prodotti per analisi di laboratorio. Progettazione, produzione e vendita di prodotti per analisi di laboratorio e articoli sanitari. Agenzia di vendita di strumentazione, reagenti e materiali di consumo per la diagnostica di laboratorio.

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.

Riferirsi al Manuale della Qualità per l'applicabilità dei requisiti della Norma ISO 13485:2012
Refer to Quality Manual for details of application to ISO 13485:2012 requirements.

Il presente certificato è soggetto al rispetto del regolamento per la certificazione dei sistemi di gestione per la qualità delle aziende.
The use and the validity of this certificate shall satisfy the requirements of the rules for the certification of company quality management systems..

Data emissione	Emissione corrente	Data di scadenza
First Issue	*Current Issue*	*Expiring date*
21/06/2014	05/06/2016	14/09/2018

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)

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CISQ is the Italian Federation of management system Certification Bodies.

ACCREDIA

SGQ N° 004 A
SSI N° 008 G
EMA N° 003 D
PRD N° 004 B
SCR N° 005 F
ISP N° 046 E
PRS N° 082 C
SGE N° 005 M

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IDNO 1003602008