

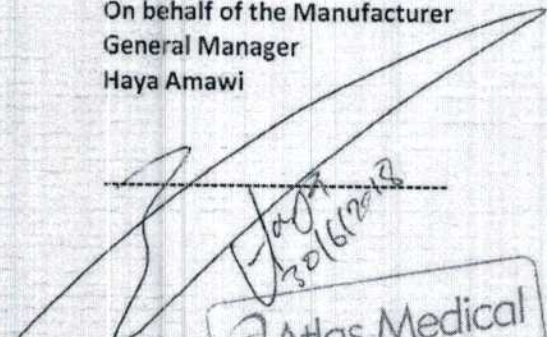

Date: 30/06/2018

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

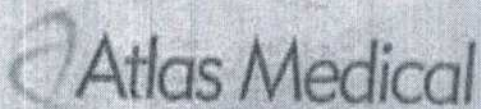

30/06/2018


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: DC11-0028

CE Declaration of Conformity

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:

Streptococcus Latex Kit

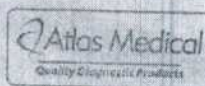
Is produced under Atlas quality system (ISO9001: 2008) and (ISO13485: 2003) supported by Lloyd's certificate and complies with the essential requirements of

**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, CB4 0WX, UK**



Atlas Medical	First issue date	Date of review	Management approval	MRXDO106
	June-2004	21.10.2015	<i>S. Ghel...</i>	10 08.02.2014



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



HIMEDIA®

For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 01st December 2017

STATEMENT

We, **HiMedia Laboratories Pvt. Ltd.**, having a registered office at A-516, Swastik Disha Business Park, Via Vadhani Industrial Estate, L.B.S. Marg, Mumbai – 400 086, INDIA, 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.

For HIMEDIA LABORATORIES PVT. LTD.,



Mr. V.M. WARKE.



DIRECTOR – SALES & MARKETING

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6116 9797 / 2500 1607 | Fax : 00-91-22-2500 2286

CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6147 1919 / 2500.3747 | Fax : 00-91-22-6147 1920 / 2500.5764 | Email : info@himedialabs.com

Web : www.himedialabs.com



... expect only quality from us™
CIN : UR5195MH082PFC006194

DECLARATION OF CONFORMITY

1) Manufacturer (Name, department): HiMedia Laboratories Pvt. Ltd.
 Address: 23 Vadhani Industrial Estate, LBS Marg, Mumbai - 86, MS, India
 and

2) European authorized representative: CEpartner4U BV,
 Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
 (on product labels printed as:
 CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) (groupnames /):

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants, Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J. Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDetect Rapid Identification Discs	NL-CA002-2013-26445	5
CCM	Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits, Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid	NL-CA002-2013-26446	6
MBP	Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits	NL-CA002-2013-26447	7

type and model numbers: 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

Mumbai, India; 2018-30-10

(Place & date of issue (yyyy-mm-dd))

Dr. G.M. Warke, Managing Director
 (name; function and signature of manufacturer)





qualityaustria
Succeed with Quality

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this qualityaustria certificate to the following organisation:

HIMEDIA

Quality Austria is
represented by an
independent
accreditation
organisation
by the IAF/ISO 17000
Society, Environmental and
Social Management
System.

Quality Austria is
represented by the
Association of the
Automotive Industry.

Quality Austria is
represented by the
Association of the
Automotive Industry.

Quality Austria is
represented by the
Association of the
Automotive Industry.

Ref: 00275/0

The current validity of the certificate is documented exclusively on the Internet under
<http://www.qualityaustria.com/en/cert> EAC: 23

This qualityaustria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
EN ISO 13485:2012

Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00275/0

Date of initial issue: 21 November 2017

Valid until: 31 March 2019

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
Konrad Scheiber
General Manager

Ing. Andreas Aichinger
Ing. Andreas Aichinger, MSc
Specialist representative



qualityaustria



Q CERTIFICATE

This Certificate confirms the application and further development of an effective
WHO GMP Compliance System
 Complying with the requirement of
WHO GMP Guidelines

Quality Austria Central Asia Private Limited
 (A Division of Peacock Global Company)
 Awards this Certificate to

Himedia Laboratories Pvt. Ltd.
 Unit I : B/4-5, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India
 Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombvli, District Thane - 421 204, Maharashtra, India
 Unit III : D-61 MIDC, Phase-II, Near Shani Mandir, Dombvli, District Thane - 421204, Maharashtra, India

Unit I : Manufacture & supply of Biosciences products for applications in Microbiology (includes Dehydrated Culture Media, Culture Media Bases, Antimicrobial Susceptibility Systems & Bacteriological Differentiation Aids), Animal Cell Culture, Plant Tissue Culture and Molecular Biology
Unit II : Manufacture and supply of Sterile Ready Prepared Media
Unit III : Manufacture and supply of Sterile Ready Prepared Media

Report No.: QACA/WHO/069
 Issue Date: 21/12/2016
 Expiry Date: 20/12/2019

qualityaustria
central asia
Succeed with Quality
 Quality Austria Central Asia Private Limited (A division of Peacock Global company)

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

A -
 Aksh Kumar
 Country Head

The Product and Systems Liability rests with the manufacturer and under no circumstances Quality Austria Central Asia Shall be held Responsible

The current validity of the certificate is documented exclusively on the internet under www.qualityaustriacentralasia.com



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

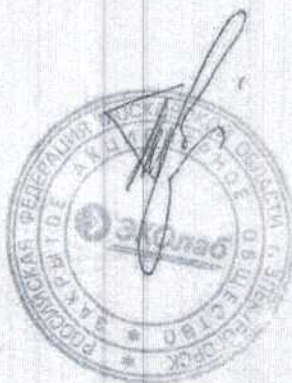
АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

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.



DECLARATION OF CONFORMITY

Appendix

- 1) **Manufacturer** (Name, department): **CJSC EKOlAb**
Address: 1 Budennogo Str., Elektrogorsk, Moscow region, 142530, Russia
- 2) **European authorized representative: CEpartner4U BV**,
Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS**;
(on product labels printed as:
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.com)

- 3) **Product(s)** (name, type or model/batch number, etc.):
- Rabbit plasma

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, etc.):
Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III
Registration nr. : pending



Elektrogorsk, Russia, 2017-11-03
V.Y. Borisov, General Director, CJSC EKOlAb
(name, function and signature of manufacturer)

Date: 2017-11-08

List of devices.

Device name	Type/model/ref number	Risk class / rule ¹	Code: EIMDS/GMDN	First date of CE-compliance
Rabbit plasma		Low risk	15011290/0	2017-11-08

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





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, Буденного str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А**

This certificate is valid from (с даты вступления в силу)
Данный сертификат действителен с (с даты вступления в силу)

2016-02-21

2019-02-21

Management director of AFNOR Certification
Генеральный директор AFNOR Certification

F. LEBEUGLE

AFNOR Certification is a member of the Bureau Veritas Group. AFNOR Certification is a member of the Bureau Veritas Group. AFNOR Certification is a member of the Bureau Veritas Group.



11, rue Francis de Provençe - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 02 06 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 15 107 000 € - 479 076 682 RCS Nanterre - immatriculation SAS



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, Буденного str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1А**

This certificate is valid from (с даты вступления в силу)
Данный сертификат действителен с (с даты вступления в силу)

2016-02-21

2019-02-21

Management director of AFNOR Certification
Генеральный директор AFNOR Certification

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11, rue Francis de Provençe - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 02 06 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 15 107 000 € - 479 076 682 RCS Nanterre - immatriculation SAS



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:

2017-09-13

Valid until:

2022-09-12



Date:

2017-06-30

S. Preiß
Sieglin Preiß

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

Page 1 of 4

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

Page 2 of 4

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

Product Service

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,



Attachment for Certificate No V1 17 08 80997 017
Supplement 001 dated 2017-08-30



Product Service

- 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. Puntig

Stefan Preis

Certification Medical Technology



ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ CERTIFICADO ◆ CERTIFICAT



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

Page 1 of 1

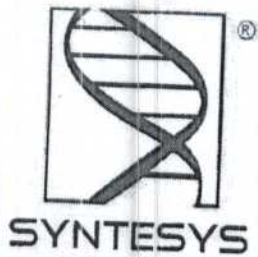


DAKKS

Deutsche
Akkreditierungsstelle
D-28611 521-01 00

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





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.

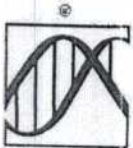
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Teolo, 02.01.2018

 **SYNTESYS S.A.S.**
DI RINALDO R & C
Via G. GALILEI, 10/3
Z.I. SELVE 35037 TEOLO (PD) - CF. IVA 03573950288
TEL. 049/9903866 R.A. FAX 049/9903867


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





SYNTESSYS



SYNTESSYS S.A.S. DI RINALDO R. & C.
35037 Z.I. SELVE DI TEOLO (PD)
VIA G. GALILEI, 10/3
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
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/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 mandatary within the European Community

Mandatario autorizzato/authorized mandatary

Indirizzo/address

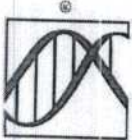
Dichiara sotto la propria responsabilità che il produttore/delcates under his own responsibility that the product:

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, rack for test tubes, Slides holder, "TESTSIMPLETS" slide; Bottles for urine collection.



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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 08/04/2000 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

(Handwritten signature)





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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 - CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
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 - IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
 - NYCE-SIGE México 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 YUQS Serbia
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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**

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*:

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 - CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
 - FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
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