

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

AlCooreen

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:
 CPartner4U , 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, HiDect 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

Dr. G.M.Warke , Managing Director

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

(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:

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

HiMedia Laboratories Pvt. Ltd.
23, Vadhani Industrial Estate L.B.S.Marg,
Ghatkopar (W), Mumbai - 400086, Maharashtra,
India

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori,
Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Differentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

The validity of the **qualityaustria** certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Registration No.: 17285/0

Date of initial issue: 29 December 2015

Valid until: 21 November 2020

Vienna, 22 November 2017

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

Scheiber

Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Specialist representative



Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is an ISO 9001:2015 certified organisation. It is authorised according to the European Accreditation Act by the DIN CERTCO (German Accreditation Body) for the ISO 9001:2015 standard in the field of Quality Management Systems.

Quality Austria is authorised by the VCA (Austrian Accreditation Body) for the ISO 9001:2015 standard in the field of Quality Management Systems.

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Quality Austria is authorised by the VCA (Austrian Accreditation Body) for the ISO 9001:2015 standard in the field of Quality Management Systems.

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



qualityaustria





qualityaustria
Succeed with Quality

CERTIFICATE

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

HiMedia Laboratories Pvt. Ltd.
23, Vadhani Industrial Estate L.B. S. Marg,
Ghatkopar (W), Mumbai - 400086, Maharashtra,
India
Unit-1, B-4-5-6, MIDC, Palkhed, Dindori,
Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Differentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

The validity of the qualityaustria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

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-1070 Vienna, Zelinkagasse 10/3

Konrad Scheiber
Konrad Scheiber
General Manager

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

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is an accredited institution for the Austrian Accreditation Act by the OAS/ÖNORM A 1700:2010 (certification of conformity with standards of the European Union).

Quality Austria is authorised by the Austrian Accreditation Authority for the accreditation of organisations for compliance with the requirements of the Austrian Accreditation Act by the OAS/ÖNORM A 1700:2010 (certification of conformity with standards of the European Union).

Quality Austria is authorised by the Austrian Accreditation Authority for the accreditation of organisations for compliance with the requirements of the Austrian Accreditation Act by the OAS/ÖNORM A 1700:2010 (certification of conformity with standards of the European Union).

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qualityaustria





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/4-6, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India

Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombivli, District Thane - 421 204, Maharashtra, India

Unit III : D-61 MIDC, Phase-II, Near Shanti Mandir, Dombivli, 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



India: 20 Dec 2016
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.

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

A-1
Alok Kumar
Country Head



ЗАО «ЭКОлаб» 142530 Московская обл, г.Электрогорск, 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

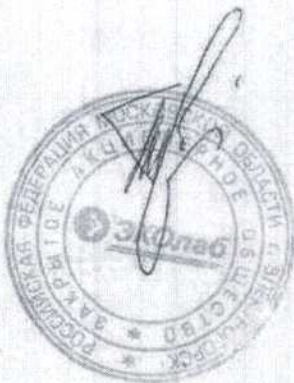
АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

Закрытое акционерное общество «ЭКОлаб» (Россия, 142530, Московская обл., г.Электрогорск, 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

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)

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

Appendix

Date: 2017-11-08

List of devices.

Device name	Type/ model/ref number	Risk class / rule ¹	Code: EMDS/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:



ZAO «EKOlab»
ЗАО «ЭКОлаб»



for the following activities:
для следующих областей деятельности:

**DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES
FOR IN-VITRO DIAGNOSTICS AND OF FINISHED MEDICINE**

**РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ
IN-VITRO ДИАГНОСТИКИ И ЛЕКАРСТВЕННЫХ СРЕДСТВ**

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 9001 : 2015

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

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

This certificate is valid from (реализована)
Данный сертификат действителен с (под) месяца (дня)

2016-02-21

until (до)

2019-02-21

Managing 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 Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00
11, rue Francis de Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00
11, rue Francis de Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00



Certificat

Certificate

N° 2007/28642.4

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



ZAO «EKOlab»
ЗАО «ЭКОлаб»



for the following activities:
для следующих областей деятельности:

**DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES
FOR IN-VITRO DIAGNOSTICS.**

**РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ
IN-VITRO ДИАГНОСТИКИ.**

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485 : 2003

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

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

This certificate is valid from (реализована)
Данный сертификат действителен с (под) месяца (дня)

2016-02-21

until (до)

2019-02-21

Managing 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 Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00
11, rue Francis de Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00
11, rue Francis de Méliès - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 42 80 00 - F. +33 (0)1 49 17 90 00

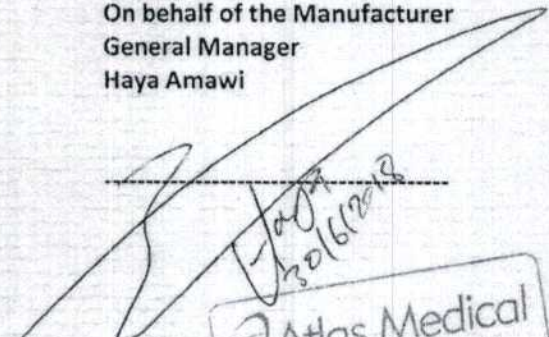
Date: 30/06/2018

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

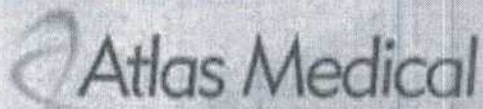

30/6/2018


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: 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:	MRXDO10FJ
	June-2004	21.10.2015	<i>S. Ghidic</i>	10 08.02.2011

Al. Gheorghiu

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 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.

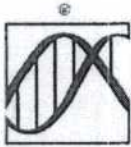
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Teolo, 02.01.2018

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


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





SYNTESYS



SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI 10/3
35037 ZI. 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



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

produttore/manufacturere

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 mandataria autorizzato entro la Unione Europea or representing the
authorized mandatar within the European Community

Mandatario autorizzato/authorized mandatar

indirizzo/address

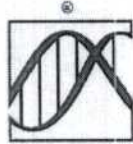
Dichiara sotto la propria responsabilità che il prodotto/declares under his own
responsability that the product:

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" slide
rack for test tubes, rack for micro test tubes,
Bottles for urine collection.

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE



SYNTESYS



SYNTESYS S.A.S. DI RINALDO R. & C.
VIA G. GALILEI 10/3
35037 ZI. 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
Polymethylmetacrylate

È conforme alle disposizioni della direttiva 90/269/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 90/269 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.

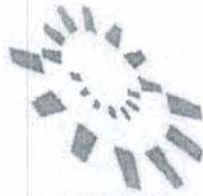
Dichiara inoltre che la documentazione tecnica di supporto alla presente dichiarazione di
conformità è conservata presso gli uffici dell'azienda e sarà posta alla disposizione di chi
la richiede/declares that all technical documents attached to this conformity statement are
filed in our company and can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

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

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



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE



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www.icim.it

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

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ 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
First issue
05/06/2013

Emissione corrente
Current issue
05/06/2016

Data di scadenza
Expiring date
14/09/2018


ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)

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Certification in the world.
IQNet is composed of more than 30
bodies and counts over 160 subsidiaries
all over the globe.*

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

CISQ is the Italian Federation
of management system
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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A ESZ N° 003 G
SGA N° 005 D PRD N° 004 B
SCR N° 006 F ISP N° 004 E
PRS N° 002 C SGE N° 003 H

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CERTIFICATO n. 7111/1
CERTIFICATE No. _____

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.

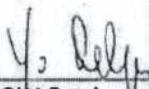
Ritornarsi al Manuale della Qualità per l'applicabilità dei requisiti della Norma ISO 13485:2012.
Refer to Quality Manual for details of application to ISO 13485:2012 requirements.

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
First Issue
21/06/2014

Emissione corrente
Current Issue
05/06/2016

Data di scadenza
Expiring date
14/09/2018


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ACCREDIA
LENGE ITALIA/IDEACREDIASIST/0

SGQ N° 004 A SSI N° 008 G
BGA N° 003 D PRD N° 004 B
SCR N° 005 F ISP N° 048 E
PRC N° 002 C SGB N° 005 M

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Signatory of EA, IAF and ILAC Mutual Recognition Agreements



Alcorum!