



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

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

Date, 2017-08-30

S. Pfeiff

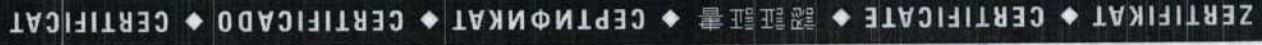
Stefan Pfeiff

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

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 05 · 80339 München · Germany

TÜV[®]



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TÜV SÜD Product Service GmbH · Zertifizierstelle



TÜV[®]

M. Lorenz



Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

Holder of Certificate: **Acon Biotech (Hangzhou) Co., Ltd.**

No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
310030 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA



Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
In Vitro Diagnostic Test Kits
and Related Instruments,
Lancet and Lancing Device**

**Applied
Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1610619

Valid from: 2016-07-15
Valid until: 2019-07-14



Date, 2016-07-08

J. Preiß
Stefan Preiß

Page 1 of 1



Stefan Preiß

Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R.China 310030

We declare under our sole responsibility that the in vitro diagnostic device:

On Call Plus Blood Glucose Monitoring System
On Call Plus Blood Glucose Meter
On Call Plus Blood Glucose Test Strip
On Call Plus Glucose Control Solution

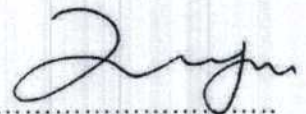
meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

**This declaration is according to Annex IV of the Directive and thus is based on approval by the notified body
TÜV SÜD Product Service GmbH, Ridlerstraße 65
80339 MÜNCHEN, Germany, notified under
No. 0123 to the EC Commission.**

Authorized Representative:
Wellkang Ltd t/a Wellkang Tech Consulting
Suite B, 29 Harley Street,
LONDON W1G 9QR, England, UK

Detailed brand information and first place date, please refer to CE Product List.

Signed this 15 day of 9, 2015
in Hangzhou, China

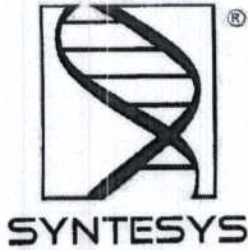


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Junny You
International Regulatory Affairs Manager
ACON Biotech (Hangzhou) Co., Ltd.



ACON BIOTECH (HANGZHOU) CO., LTD.
No.210 Zhenzhong Road, West Lake District, Hangzhou, P.R.China, 310030
Tel: +86-571-87963569 Fax: +86-571-87963570 E-mail: css@aconlab.com.cn





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.F.P. 03573950288
TEL. 049 9903866 R.A. FAX 049/9903867


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





SYNTESYS



SYNTESYS S.A.S. DI RINALDO RUGGERO & C.
35037 ZI SELVE DI TEOLO (PD)
VIA G. GALILEI, 10/3
COD. FISCALE P.IVA N. REG. IMP. PADOVA 03573950298
TEL. +39 049 9903866 R.A. FAX +39 049 9903867
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 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, tazzina 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.



SYNTESYS

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 06/09/2000 n° 332 allegato I
(requisiti essenziali) ed è fabbricato in accordo ai requisiti di cui all'Allegato III della
sopra citata direttiva / It meets the CE Directive 98/79 CE about in vitro diagnostic device
specifications established by the Italian law n. 332, dated 6th September 2000. The device is
made according to the specifications of the III attached of the above-mentioned directive.

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

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

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



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABILE LABWARE

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABILE LABWARE



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*:

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



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



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

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

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

has implemented and maintains a

Quality Management System

for the following scope:

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

which fulfils the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2018-06-04**

First issued on: **2014-06-21**

Expires on: **2019-06-04**

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

Registration Number: IT-93779



Alex Stoichitoiu
President of IQNET



Ing. Claudio Provetti
President of CISQ

IQNet Partners*:

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



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