



San Diego July 11<sup>th</sup>, 2018

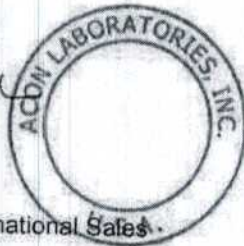
We, ACON Laboratories Inc. having a registered office at 10125 Mesa Rim Road. San Diego, CA 92121, USA assign SRL Sanmedico having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 93/42/EEC, 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



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



*S. Preiß*  
 Stefan Preiß

**Date,** 2017-08-30

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

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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. Pauer*

Stefan Preiß

Certification Medical Technology





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

*S. Preis*  
Stefan Preis



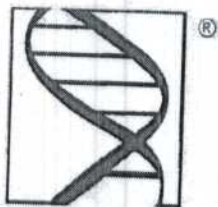
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DAKKS

Deutsche  
Akkreditierungsstelle  
D-ZM-11521-01-01

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





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

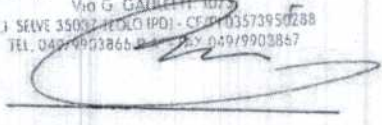
## AUTHORIZATION LETTER

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.

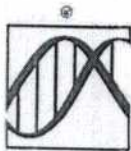
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Teolo, 02.01.2018

 **SYNTESYS S.A.S.**  
DI RINALDO R & C  
Via G. GALILEI, 10/3  
Z.I. SELVE 35037 TEOLO (PD) - CF. 03573950288  
TEL. 0499903866 R.A. FAX 0499903867

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





SYNTESYS



SYNTESYS S.A.S. DI RINALDOR & C.  
25037 ZI. SELVE DI TEOLO (PD)  
VIA G. GALILEI, 10/3  
COD. FISCALE PIVA NRES IMP. PADOVA 03573950288  
TEL. +39 049 9903866 RA. FAX. +39 049 9903867  
E-MAIL INFO@SYNTESYS.IT - WEB WWW.SYNTESYS.IT

DICHIARAZIONE DI CONFORMITA'  
Conformity declaration



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

Produttore/manufacturer

SYNTESYS 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

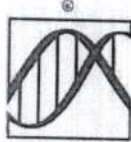
Dichiara sotto la propria responsabilità che il prodotto/declares under his own responsibility that the product:

Denominazione degli articoli  
products/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, baccinette per distacco ed estrazione del coagulo, pinzette in polistirolo monouso, provette monouso in plastica, tappi elettati 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.

PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE LABWARE



SYNTESYS



SYNTESYS S.A.S. DI RINALDOR & C.  
25037 ZI. SELVE DI TEOLO (PD)  
VIA G. GALILEI, 10/3  
COD. FISCALE PIVA NRES IMP. PADOVA 03573950288  
TEL. +39 049 9903866 RA. FAX. +39 049 9903867  
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 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 06/04/2000 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 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 Ruggiero



PRODOTTI E STRUMENTAZIONE PER ANALISI DI LABORATORIO - DISPOSABLE 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 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 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

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](http://www.iqnet-certification.com)

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

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**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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