



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. Freil
Stefan Freil

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

Page 1 of 4



TÜV SÜD Product Service GmbH - Zertifizierstelle · Riederstraße 65 · 80329 München · Germany

Page 2 of 4

TÜV SÜD Product Service GmbH · Zertifizierstelle · Riederstraße 65





Product Service

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

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.



TÜV SÜD Product Service GmbH · Zentralfürsorge · Hindertstraße 65 · 81639 München · Germany



Product Service

Attachment for Certificate No V1 17 08 80997 017

Supplement 001 dated 2017-08-30

- 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. Preis

Stefan Preis

Certification Medical Technology



TÜV SÜD Product Service GmbH · Zentralfürsorge

U. Coorner



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 TUV 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

Stefan Preiß

Page 1 of 1

DAKKS
Deutsche



Declaration of Conformity

ACON Laboratories, Incorporated
10125 Mesa Rim Road
San Diego, CA 92121 USA

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

Foresight HSV 1 IgG EIA Test Kit
Foresight HSV 2 IgG EIA Test Kit
Foresight HSV 1/2 IgG EIA Test Kit
Foresight HSV 1 IgM EIA Test Kit
Foresight HSV 2 IgM EIA Test Kit
Foresight HSV 1/2 IgM EIA Test Kit

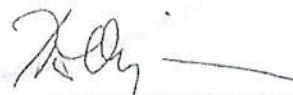
classified as others of the directive 98/79/EC,

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

This self-declaration is according to Annex III (excluding Section 6) of the Directive.

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 8th day of Oct, 2013
in San Diego, CA USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs
ACON Laboratories, Inc.



10125 Mesa Rim Road · San Diego, CA 92121 · USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com



Declaration of Conformity

ACON Laboratories, Incorporated
10125 Mesa Rim Road
San Diego, CA 92121 USA

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

Foresight CMV IgG EIA Test Kit
Foresight CMV IgM EIA Test Kit

classified as List B in Annex II of the directive 98/79/EC,
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:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 14 day of March, 2014
in San Diego, CA USA



Qiyi Xie, MD, MPH
Senior Staff, Regulatory Affairs & Clinical Affairs
Acon Laboratories, Inc.



10125 Mesa Rim Road · San Diego, CA 92121 · USA · Tel: (858) 875-8000 · Fax: (858) 875-8099
E-mail: info@aconlabs.com



STATEMENT

We, "Technology-Standard" Ltd. having a registered office at 116/95, Kalinin Prospekt, Barnaul, 656037, Russia, 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/EC.

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

"Tecnology-Standart" Ltd
116/95 Kalinin Prospekt
City of Barnaul, 656037, Russia
SRL SANMEDICO
A. Corobceanu street 7A, apt. 9,
Chişinău MD-2012, Moldova

Date: 01.12.2017

Director: Mr. A. B. Komol

Signature: _____



ЗАЯВЛЕНИЕ

Мы, ООО «Технология-Стандарт», имеющее зарегистрированный офис по адресу 116/95, проспект Калинина, г. Барнаул, 656037, Россия, поручают SRL SANMEDICO, имеющую зарегистрированный офис на улице А.Коробчану 7А, кв. 9, Кишинёв MD-2012, Молдова, быть в качестве уполномоченного представителя в соответствии с условиями директивы 98/79/ЕС.

Мы заявляем, что упомянутая выше компания имеет право регистрировать, уведомлять, обновлять или возобновлять регистрацию медицинских изделий на территории Республики Молдова.

ООО Фирма «Технология-Стандарт»
656037 Россия г.Барнаул,
пр-кт Калинина 116/95
SRL SANMEDICO,
г. Кишинёв MD-2012, Молдова
ул. А.Коробчану 7А, кв. 9

Дата: 01.12.2017

Директор: А. Б. Комол

Подпись: _____





CERTIFICATE

This certifies that the Quality management system for medical devices of company

«Technology-Standard» LTD

116/95, Kalinin Prospekt, City of Barnaul, 656037
RUSSIA

*has been assessed by 3EC International
and found to be in conformance with the following standard:*

EN ISO 13485:2016

for the following scope:

DEVELOPMENT, PRODUCTION AND SALES OF DIAGNOSTIC KITS AND REAGENTS FOR IN VITRO DIAGNOSTICS OF HAEMOSTASIS SYSTEM

Certificate No.: M-0379/18

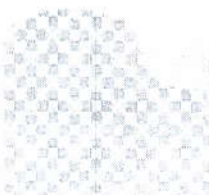
Date of issuance: July 26th, 2018

Original date of approval: August 5th, 2016

This certificate is valid from July 26th, 2018 to August 4th, 2019 on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

This certificate fully supersedes previous certificate No. M-0379/16 issued on August 5th, 2016.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic



Dr. Katarina Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with the scope of certification certificate No. Q-054 for certification of Quality management systems for medical devices.



Handwritten signature



Declaration of Conformity

Document ref.: DoC2015 vs. 02
Page: 1 of 6

DECLARATION OF CONFORMITY

- 1) **Manufacturer** (Name, department): "Technology-Standard" Ltd
Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia
- 2) **European authorized representative**: CEpartner4U BV,
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
CEpartner4U, ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu

3) **Product(s)** (name, type or model/batch number, etc.):
- Kits and reagents for in vitro diagnostics of haemostasis system
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
 Registration nr.: NL-CA002-2015-34420



Barnaul, Russia; 2015-03-17
 Andrey Momot, Director "Technology-Standard" Ltd
 (Place & date of issue (yyyy-mm-dd)) (name, function and signature of manufacturer)



Declaration of Conformity

Document ref.: DoC2015 vs. 02
Page: 2 of 6

Appendix

Date: 2015-02-09

List of devices:

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Techplastin-test» The kit of reagents for the determination of prothrombin time	607, 131, 608, 140	Low	13 02 01 01/ 30539	09.02.2015
«SFCM-test» The kit of reagents for the determination of soluble fibrin monomer complexes in blood plasma	081, 007	Low	13 02 03 03/ 43421	09.02.2015
«APTT-test» The kit of reagents for the determination of activated partial thromboplastin time	152, 001	Low	13 02 01 02/ 32392	09.02.2015
«Tech-Fibrinogen-test» The kit of reagents for the determination of fibrinogen concentration in blood plasma	324, 094, 225	Low	13 02 02 01/ 30541	09.02.2015
«ChromoTech-Plasminogen» The kit of reagents for the determination of plasminogen concentration in blood plasma	092	Low	13 02 05 05/ 30578	09.02.2015

* See EDMS codes: <http://www.edms-ivd.be/> (products classification)



Handwritten signature

Declaration of Conformity



Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«ChromoTech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Plasma-control» The kit of control blood plasma for the study of haemostasis	400	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII-test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-EI-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015

Declaration of Conformity



Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	012	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» Pathologic plasma	013	Low	13 02 50 02/ 32394	09.02.2015
«Techplasin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	144	Low	13 02 01 01/ 30539	09.02.2015
«Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of Xlla-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015



Handwritten signature



Declaration of Conformity

Document ref.: DoC2015 vs. 02
Page: 5 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«MultiTech-Fibrinogen» The kit of reagents for the determination of fibrinogen concentration by automated and semi-automated coagulometers	711, 712	Low	13 02 02 01/ 30541	09.02.2015
«Fibrinogen-Calibrator» The kit of calibrators for the determination of fibrinogen concentration	714	Low	13 02 50 02 / 39413	09.02.2015
«ADP» The kit of reagents for the determination of ADP-aggregation of platelets	030	Low	13 02 04 01/ 30569	09.02.2015
Ristomycin The kit of reagents for the determination of ristomycin-aggregation of platelets	197	Low	13 02 04 01/ 30569	09.02.2015
«Collagen» The kit of reagents for the determination of collagen-aggregation of platelets	095	Low	13 02 04 01/ 30569	09.02.2015
«Adrenaline» The kit of reagents for the determination of adrenaline-aggregation of platelets	031	Low	13 02 04 01/ 30569	09.02.2015



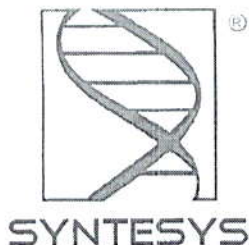
Declaration of Conformity

Document ref.: DoC2015 vs. 02
Page: 6 of 6

Device name	Type/model/ref number	Risk class	Code:EMDS/GMDN	First date of CE-compliance
«Aggrescreen-test» The kit of reagents for the express assessment of platelet haemostasis	010	Low	13 02 04 01/ 30569	09.02.2015
«Human platelets»	132	Low	13 02 04 01/ 32409	09.02.2015
«Sodium citrate» A reagent for the stabilization of blood in the study of haemostasis	028	Low	13 02 80 02/ 0	09.02.2015



Handwritten signature



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.

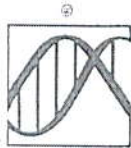
Teolo, 02.01.2018



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

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





SYNTESYS



SYNTESYS S.A.S. DIRINALDO & 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 Ruggiero legale rappresentante della ditta:
The undersigned, Rinaldo Ruggiero legal representative of the company:

produttore/manufacturor

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

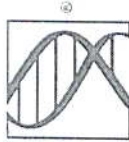
Dichiana sotto la propria responsabilità che il prodotto/declares under his own
responsability that the product:

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 Hailer, 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

Materiale/Material

Polipropilene, Polistirolo, Polietilene e
Poliimetilmetacrilato
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.

Dichiaro 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

U. Cozzani



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
 - FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa
 - IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSA
 - 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
- IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI



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



IQNet

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 B...
- FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa R...
- IRAM Argentina IQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI
- 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
- IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI



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