YourTrustedPartner

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,

ACON LABORATORIES, INC.

Jassy Alvarenga

Account Manager, International Sales

ACON Laboratories

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Stefan Preiß

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

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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,

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Stefan Preiß

Certification Medical Technology

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

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RASPUNDERE LIMITATA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ 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:

tuv-sud.com/ps-cert

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

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZE-12021-01-00

TÜV®

REPUBLICA MOLDOVA, mun. CHIȘINĂU PENTRU CONTRACTE ȘI FACTURI "SANMEDICO" S.R.L. IDNO 1003602008154 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

DAkkS CRT2 / 10.13

Declaration of Conformity

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

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

Foresight® TSH 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:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

Signed this 02 day of November, 2017
in San Diego, CA USA

Jinn-nan Lin
President
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 Total T3 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 26 day of Aug, 2014
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 Total T4 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 26 day of Aug. 2014
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

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO"
S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

XEMA CO., Ltd.
bldg. 48/4, 9th Parkovaya str., 105264, Moscow, Russia
Tel./Fax: +7 (495) 510-57-07, +7 (495) 737-39-36
E-mail: info@xema.ru, info@xema-medica.com
Internet: www.xema.ru, www.xema-medica.com

STATEMENT

We, XEMA Co., Ltd. having a registered office at 48, 9th Parkovaya st, 104264 Moscow, Russia, assign Sanmedico Srl. having a registered office at str. A. Corobceanu 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.

Date : November, 29, 2017

Signature:

Andrei P. Redkin

Deputy general manager

Polmed.de
Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

Nr. AR/IVMD/Xema/12-2016

Issued on the basis of the Declaration of conformity and registration taking into account Article 10 of Directive 98/79/EC on In Vitro Diagnostic Medical Devices and Medical Devices Act (MPG) § § 5,25,29,30)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 98/97/EG Artikel 10 über In-vitro-Diagnostik a und Medizinproduktgesetz (MPG) §§ 5,25,29,30

Manufacturer: Hersteller	**Xema Co., Ltd.** bld.4, 48, The 9th Parkovaya str. Moscow 105264, RUSSIA, info@xema.ru; www.xema.ru
Product name: Produkt	**See annex to the Certificate** Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	**In Vitro Diagnostic Medical Devices** In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	**Common/ Other IVD** Sonstige IVD-Produkte
Conformity Module: Konformitätsmodul	**Module A (EC Declaration of Conformity) (Annex III, except point6, Directive 98/79/EC)** Modul A (EG-Konformitätserklärung) (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG)
Lead Competent Authority: Zuständige Behörde	**DIMDI** – German Institute of Medical Documentation and Information **DIMDI** – Deutsches Institut für Medizinische Dokumentation und Information
Product Registration Ref. No.: (Per Article 10, Directive 98/79/EC) Produkt Registrationsnummer (Gemäß Artikel 10 der Richtlinie 98/79 / EG)	**See annex to the Certificate** Siehe Anhang zum Zertifikat

Date of issue: **2016-12-31**
Das Ausstellungsdatum

Valid to: **2019-12-31**
Gültig bis

Vertretung und Repräsentanz Polmed.de D-73773 Aichwald Steinacker 5

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Polmed.de

Polmed.de
Vertretung und Repräsentanz

Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragistaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
1.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA Cat. Nr K131	DE/CA37/IVD/13/44
2.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA Cat. Nr K132	DE/CA37/IVD/13/43
3.	MPO ANCA	K133	aMPO EIA Cat. Nr K133	DE/CA37/IVD/13/42
4.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	Anti-tTG IgG EIA Cat. Nr K160; Anti-tTG IgA EIA Cat. Nr K161	DE/CA37/IVD/13/41
5.	GLIADIN ANTIBODIES	K180 K181 K182A K182G	Gliadin IgG EIA Cat. Nr K180; Gliadin IgA EIA Cat. Nr K181 ; Deamidated Gliadin IgA EIA, Deamidated Gliadin IgG EIA	DE/CA37/IVD/13/40
6.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA Cat. Nr K200	DE/CA37/IVD/13/39
7.	THYROID STIMULATING HORMONE	K201 K201A	TSH EIA Cat. Nr K201; TSH Plus EIA Cat. Nr K201A	DE/CA37/IVD/13/38
8.	LUTEINISING HORMONE	K202	LH EIA Cat. Nr K202	DE/CA37/IVD/13/37
9.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA Cat. Nr K203	DE/CA37/IVD/13/36
10.	HUMAN GROWTH HORMONE	K204	GH EIA Cat. Nr K204	DE/CA37/IVD/13/35
11.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	HCG EIA Cat. Nr K205	DE/CA37/IVD/13/34
12.	PROLACTIN	K206	Prolactin EIA Cat. Nr K206	DE/CA37/IVD/13/33
13.	PROGESTERONE	K207 K207S	Progesterone EIA Cat. Nr K207 ; Salivary Progesterone EIA	DE/CA37/IVD/13/32
14.	ESTRADIOL	K208	Estradiol EIA Cat. Nr K208	DE/CA37/IVD/13/31
15.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209 K209S	Testosterone EIA Cat. Nr K209 ; Salivary Testosterone EIA	DE/CA37/IVD/13/30
16.	CORTISOL	K210 K210S	Cortisol EIA Cat. Nr K210 ; Salivary Cortisol EIA	DE/CA37/IVD/13/29
17.	TRIIODOTHYRONINE	K211	T3 EIA Cat. Nr K211	DE/CA37/IVD/13/28
18.	THYROXINE	K212	T4 EIA Cat. Nr K212	DE/CA37/IVD/13/27
19.	FREE TRIIODOTHYRONINE	K213	Free T3 EIA Cat. Nr K213	DE/CA37/IVD/13/26
20.	FREE THYROKINE	K214	Free T4 EIA Cat. Nr K214	DE/CA37/IVD/13/25
21.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEA-S EIA Cat. Nr K215	DE/CA37/IVD/13/24
22.	17 OH PROGESTERONE	K217	17-OH-Progesterone EIA Cat. Nr K217	DE/CA37/IVD/13/22
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr K222	DE/CA37/IVD/13/23
24.	CANCER ANTIGEN 19-9	K223	CA 19.9 EIA Cat. Nr K223	DE/CA37/IVD/13/21
25.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA Cat. Nr K224	DE/CA37/IVD/13/20

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

"SANMEDICO" S.R.L. IDNO 1003602008154

Polmed.de
Vertretung und Repräsentanz

Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
26.	ALPHAFETOPROTEIN	K225	AFP EIA Cat. Nr K225	DE/CA37/IVD/13/19
27.	CANCER ANTIGEN 15-3	K226	M12 (CA 15.3) EIA Cat. NrK226	DE/CA37/IVD/13/18
28.	OTHER CANCER ANTIGENS	K227 K228	MUC1 M22 EIA Cat. Nr K227; MUC1 M20 EIA Cat. Nr K228	DE/CA37/IVD/13/17
29.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA Cat. Nr K232	DE/CA37/IVD/13/16
30.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	Free beta HCG EIA Cat. Nr K235	DE/CA37/IVD/13/15
31.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA Cat. Nr K238	DE/CA37/IVD/13/14
32.	OTHER OTHER PLASMA PROTEINS	K240	Alveomucin EIA Cat. Nr K240	DE/CA37/IVD/13/13
33.	C-REACTIVE PROTEIN	K250	CRP EIA Cat. Nr K250	DE/CA37/IVD/13/12
34.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA Cat. Nr K268	DE/CA37/IVD/13/11
35.	TROPONIN (T + I)	K291	Troponin I EIA Cat. Nr K291	DE/CA37/IVD/13/10
36.	IMMUNOGLOBULIN G	K271	Total IgG EIA Cat. Nr K271	DE/CA37/IVD/13/9
37.	IMMUNOGLOBULIN G SUBCLASS REAGENTS	K272 K274	IgG2 EIA Cat. Nr K272; IgG4 EIA Cat. Nr K274	DE/CA37/IVD/13/8
38.	IMMUNOGLOBULIN A	K275	Total IgA EIA Cat. Nr K275	DE/CA37/IVD/13/7
39.	IMMUNOGLOBULIN M	K277	Total IgM EIA Cat. Nr K277	DE/CA37/IVD/13/6
40.	RHEUMATOID/AUTOIMMUNE CONTROLS	KQ13 KQ14 KQ15	AutoQon AT immunoassay control set Cat. Nr KQ13; AutoQon ANA/ENA immunoassay control set Cat. Nr KQ14; AutoQon ACL immunoassay control set Cat. Nr KQ15	DE/CA37/IVD/13/5
41.	HORMONE CONTROLS	KQ21	HormoQon immunoassay control set Cat. Nr KQ21	DE/CA37/IVD/13/4
42.	TUMOUR MARKER CONTROLS	KQ22	OmaQon immunoassay control set Cat. Nr KQ22	DE/CA37/IVD/13/3
43.	CYFRA 21-1	K236	CYFRA 21-1 EIA	DE/CA37/IVD/13/45
44.	CANCER ANTIGEN 72-4	K244	CA 72-4 EIA	DE/CA37/IVD/13/46
45.	NEONATAL THYROID STIMULATING HORMONE	K201N	TSH-Neo EIA	DE/CA37/IVD/13/47
46.	ESTRIOL	K218	Free Estriol EIA	DE/CA37/IVD/13/48
47.	IMMUNOGLOBULIN E - MONOTEST/MONORESULT - MULTI AG	K200S	Specific IgE EIA	DE/CA37/IVD/13/49
48.	KAPPA AND LAMBDA CHAIN	K279K K279L	Free kappa lgg light chain EIA, Free lambda lgg light chain EIA	DE/CA37/IVD/13/50
49.	TRYPSIN NEONATAL	K242	Neonatal IRT EIA Cat. Nr K242	DE/CA37/IVD/13/51
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Polmed.de
Vertretung und Repräsentanz

Annex to the Certificate No.:
Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	DE/CA37/IVD/13/53
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	DE/CA37/IVD/13/67
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	DE/CA37/IVD/13/66
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	DE/CA37/IVD/13/65
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	DE/CA37/IVD/13/64
56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	DE/CA37/IVD/13/63
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	DE/CA37/IVD/13/62
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	DE/CA37/IVD/13/61
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	DE/CA37/IVD/13/60
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	DE/CA37/IVD/13/59
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	DE/CA37/IVD/13/58
62.	GIARDIA LAMBLIA	K171	Giardia lamblia Total Ab EIA (Cat. Nr 171)	DE/CA37/IVD/13/57
63.	OTHER TUMOUR MARKER RAPID TESTS	X22OV	XEMAtestOvaScreen (Cat. Nr X22OV)	DE/CA37/IVD/13/56
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	DE/CA37/IVD/13/55
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	DE/CA37/IVD/13/54
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	DE/CA37/IVD/13/68
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	DE/CA37/IVD/13/72E
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	DE/CA37/IVD/13/71E
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	DE/CA37/IVD/13/70E
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	DE/CA37/IVD/13/69E

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

Represented in the EC by Polmed.de
Steinacker 5, 73773 Aichwald, Germany
email: info@polmed.de
tel: +49 711 52853279

Vertretung und Repräsentanz Polmed.de D-73773 Aichwald Steinacker 5

Date: **December 31, 2016**

Polmed.de

REPUBLICA MOLDOVA, mun. CHIȘINĂU PENTRU CONTRACTE SI FACTURI "SANMEDICO" S.R.L. SOCIETATEA CU RASP. LIMITATĂ IDNO 1003602004

Valid with the Extract from the database www.dimdi.de (German Institute for Medical Documentation)
Gilt nur mit Auszug aus der Datenbank www.dimdi.de (Deutsche Institut Für Medizinische Dokumentation)

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
53899-2009-AQ-MCW-FINAS

Initial certification date:
22 May 2009

Valid:
14 March 2018 - 28 February 2019

This is to certify that the management system of

XEMA CO., LTD.

bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2003

This certificate is valid for the following scope:
DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

Place and date:
Moscow, 14 March 2018

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

For the issuing office:
DNV GL – Business Assurance
Trekhprudny per. 9 build. 2, office 406,
Moscow, Russian Federation

S. Groubine

Serguei Groubine
Management Representative

Appendix to Certificate

XEMA CO., LTD.
Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
XEMA CO., LTD.	bldg. 48, 9-th Parkovaya str., Moscow, Russian Federation, 105264	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.
XEMA Co., LTD (production site)	Trubetskaya str., 2B, Balashikha, Moscow region, Russian Federation, 125000	DESIGN, DEVELOPMENT, MANUFACTURING AND SALES OF KITS FOR IVD USE.

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info
ACCREDITED UNIT: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Kellosaarenna 5, 02150 Espoo, Finland. TEL: +358 10 292 4200. assurance.dnvgl.com

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO"
S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 1-408-855-0061
Fax: 1-408-855-0063
E-mail: info@lumiquick.com
Website: www.lumiquick.com

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 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.

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President

LumiQuick
Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, California 95054 USA
Tel: 1-408-855-0061 info@lumiquick.com
Fax: 1-408-855-0063 www.lumiquick.com

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

LumiQuick Diagnostics, Inc.
2946 Scott Blvd
Santa Clara
California
95054
USA

Holds Certificate No: **FM 574919**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution of in vitro diagnostics test kits and reagents used in the diagnosis and management of disease status, including Infectious Diseases tests, Drugs of Abuse tests, Cardiac Monitor tests, Cancer Marker tests, Fertility Hormone tests, ELISA tests & Urine Chemistry tests.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2011-10-20
Latest Revision Date: 2017-10-09

Effective Date: 2017-10-20
Expiry Date: 2019-02-28

...making excellence a habit.™

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Cardiac Marker Test Devices	
QuickProfile Troponin I Serum Test Card	75001
QuickProfile Troponin I Whole Blood Test Card	75002
QuickProfile Cardiac Panel Serum Test Card	75003
QuickProfile Cardiac Panel Whole Blood Test Card	75004
QuickProfile Myoglobin Serum Test card	75005
QuickProfile Myoglobin Whole Blood Test Card	75006
QuickProfile CK-MB Serum Test Card	75007
QuickProfile CK-MB Whole Blood Test Card	75008
QuickProfile Troponin I Strip	75009
QuickProfile CK-MB Strip	75010
QuickProfile Myoglobin Strip	75011

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602005154
SOCIETATE CU RASPUNDERE LIMITATA

EC_Declaration_Letter_Emergo_E2R0_NewAddress

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
H. Pylori Ab/Ag Test Devices	
QuickProfile H. Pylori Antigen Test Card	71020
QuickProfile H. Pylori Antibody Test Card Whole Blood	71024
QuickProfile H. Pylori Antibody Test Card-Serum	71046
QuickProfile H. Pylori Antigen Test Strip	71061
QuickProfile H. Pylori Antibody Serum Test Strip	71064
QuickProfile H. Pylori Antibody WB Test Strip	71086

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

REPUBLICA MOLDOVA, mun. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EC_Declaration_Letter_Emergo_E2R0_NewAddress

LumiQuick Diagnostics, Inc.
2946 Scott Blvd., Santa Clara, CA 95054, USA

Tel: 408-855-0061
Fax: 408-855-0063
E-mail: info@LumiQuick.com
Web: www.lumiquick.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	**Model/number**
Fecal Occult Blood Test Devices QuickProfile Fecal Occult Blood Test Card QuickProfile Fecal Occult Blood Test Strip	 72001 72006

MANUFACTURER		
Name of company	**Address**	**Representative**
LumiQuick Diagnostics, Inc.	2946 Scott Blvd. Santa Clara, CA 95054 USA	Jeff Wang

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	**Route to compliance**	**Standards applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	ISO 13485:2003

LumiQuick Diagnostics, Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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/PI 03573950288
TEL. 049/9903866 R.A. - FAX 049/9903867

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

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO"
IDNO 1003602008454

SYNTESYS

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

DICHIARAZIONE DI CONFORMITA'
Conformity declaration

CE

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

produttore/*manufacturer*

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, 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.*

SYNTESYS

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

Materiale/*Material*	Polipropilene, Polistirolo, Polietilene e Polimetilmetacrilato *Polypropylene, Polystyrene, Polyethylene and Polymetilmetacrylate*

È conforme alle disposizioni della direttiva 98/79/CE concernente i dispositivi medici diagnostici in vitro e recepito in Italia con D.L. del 08/09/2000 n° 332 allegato 1 (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 statment 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

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO"
IDNO 1003602008154

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

0774GM_03_EN

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 *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

0774CM_03_EN

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.

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/EC.

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.

Подпись:

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SNAS
Reg. No. 305/Q-054

3EC®
International

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 13485:2012

(ISO 13485:2003 + Cor 1:2009)

for the following scope:

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

Certificate No.: M-0379/16 **Date of Issuance: August 5th, 2016** **Original date of approval: August 5th, 2016**

This certificate is valid from **August 5th, 2016** to **March 1st, 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.

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

Dr. Katarína 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 accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: "Technology-Standard" Ltd

Address: 116/95, Kalinin Prospekt, Barnaul, 656037, Russia

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

Andrey Momot, Director "Technology-Standard" Ltd
(name, function and signature of manufacturer)

Appendix

Date: 2015-02-09

List of devices.

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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
«SFMC-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

[1] See EDMS codes: http://www.edma-ivd.be/ (products classification/Preference GMDN code

"SANMEDICO" S.R.L. IDNO 1003602008154

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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-El-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

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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
«Techplastin-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 XIIa-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015

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Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	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

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Atlas Medical

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

Atlas Medical
Diagnostic Products

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

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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

UKAS MANAGEMENT SYSTEMS
001

Declaration Ref No: DC11-0051

Atlas Medical

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

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:

See Attached list

- Comply with all essential requirements (AnnexI) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2003) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2012 , EN ISO 13532: 2002, 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.

Manufacturer
Atlas Medical
William James House, Cowley Rd.,
Cambridge, CB4 0WX, UK

Atlas Medical
Quality Diagnostic Products

Atlas Medical	Issue date	Date of review	Management approval	MRXDO10F.10 08.02.2011
	December.2011	21st of March,2018		

Atlas Medical
CE Declaration of Conformity
According to Annex III of the IVD Directive 98/79/EC

Catalouge No	Description
Latex Kits	
8.00.00	CRP latex Kits
8.00.01	CRP latex Kits with buffer
8.00.02	ASO latex Kits
8.00.03	ASO latex Kits with buffer
8.00.04	RF Latex Kits
8.00.05	RF Latex Kits with buffer
8.00.07	hCG Latex Kits
8.00.08	IM (Hourse Stroma)Latex Kits
8.00.11	SLE Latex kits
8.00.12	Staphylococcus Latex Kits
8.00.13	Streptococcus Latex kits
8.00.15	E.Coli Latex Kits
8.00.16	Rota Virus Latex Kits
8.00.17	D-Dimer Latex kits
8.00.21	Waaler rose Latex Kits
Febrile Antigen Kits	
8.01.00	Brucella Rose Bengal
8.01.01	Salmonella OA Reagent
8.01.02	Salmonella OB Reagent
8.01.03	Salmonella OC Reagent
8.01.04	Salmonella OD Reagent
8.01.05	Salmonella HA Reagent
8.01.06	Salmonella HB Reagent
8.01.07	Salmonella HC Reagent
8.01.08	Salmonella HD Reagent
8.01.10	Brucella Abortus Reagent
8.01.11	Brucella Melitensis Reagent
8.01.12	Proteus OX2 Reagent
8.01.13	Proteus OX19 Reagent
8.01.14	Proteus OXK Reagent
8.01.15	Brucella Antigens Kits
8.01.16	Salmonella Antigen Sets
8.01.17	Febrile Antigen Set (10 Antigens)
8.01.17	Febrile Antigen Set (10 Antigens) With controls
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD)
8.01.18	Salmonella Antigen Set, Widal Kit (6 Antigens: OA, OB, OD, HA, HB, HD) with controls
8.01.19	Febrile Antigens Positive Control
8.01.20	Febrile Antigens Negative Control
Co-aggulation Reagents	
8.02.40	PT Calcium Rabbit Brain Thromboplastin, liquid
8.02.41	APTT (PTT) Micronised Silica Platelet Substitute, Liquid
8.02.60	Normal Coaggulation Control
8.02.61	Abnormal Coaggulation Control
8.02.44	PT Kit
8.02.45	APTT (PTT) Kit

Catalouge No	Description
8.02.48	Calcium Chloride
8.02.69	Fibrinogen Reagent
Hemoglobin Reagents	
8.02.46	Drabkins Reagent, 40x
8.02.50	Hemoglobin Standard, 15g/dL
Sickle Cell Kits	
8.02.67	Sickle Cell Kit
8.02.68	Sickle Cell positive & negative control set
Urine Reagent Strips	
8.03.00	URS 1 Parameter: Glucose
8.03.01	URS 1 Parameter: Protein
8.03.02	URS 1 Parameter: Ketone
8.03.03	URS 2 Parameters:Glucose,Ketone
8.03.04	URS 2 Parameters:Glucose, Protein
8.03.05	URS 2 Parameters: Urobilinogen, Bilirubin (Liver Function Test)
8.03.06	URS 3 Parameters: Protein, pH, Glucose
8.03.07	URS 3 Parameters:Glucose, Protein, Ketone
8.03.15	URS 9 Parameters:Nitrite, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.16	URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.03.17	URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.03.18	URS 11 Parameters: Leucocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
Fertility Rapid Tests	
8.04.00	hCG Test Cassette, Urine
8.04.01	hCG Test Cassette, Urine/Serum
8.04.04	hCG Test Strip, 5.0mm, Urine
8.04.05	hCG Test Strip, 3.5mm, Urine
8.04.06	hCG Test Strip, 2.5mm, Urine
8.04.10	hCG Test Strip, 5.0mm, Urine/Serum
8.04.12	hCG Test Strip, 2.5mm, Urine/Serum
8.04.88	hCG Test Strip, 3.5 mm, Urine/Serum
8.04.90	hCG Test Strip, 2.5 mm, Urine/Serum
8.04.14	LH Test Cassette, Urine
8.04.15	LH Test Strip, 3.5mm, Urine
Infectious Disease Rapid Test - Antibody Testing	
8.04.20	H.pylori Antibody Test Cassette, Whole Blood/Serum/Plasma

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