ACON

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 PENTRU CONTRACTE SI FACTURI "SANMEDICO" S.R.L. IDNO

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ 認証書 ◆ 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

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ 認証書 ◆ 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

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

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602009164
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

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 EIATest 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

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602005154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

Foresight® Toxoplasma IgG EIA Test Kit

classified as Annex II List B 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.

Certifcate No. V1 16 06 80997 012
valid 2016/08/24 to 2017/09/12

Authorized Representative:
MDSS
Schiffgraben 41
30175 Hannover, Germany

Signed this 14th day of Sep, 2016
in San Diego, CA, USA

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

ACON
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. CHIȘINĂU
PENTRU CONTRACTE ȘI FACTURI
"SANMEDICO" S.R.L.
IDNO 1006602008154
SOCIETATE CU RĂSPUNDERE LIMITATĂ

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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

TÜV

"SANMEDICO" S.R.L.

IDNO 1003602008154

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-Diagnostika 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 Vertragsstaaten 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.

REPUBLICA MOLDOVA, mun. CHISINAU PENTRU CONTRACTE SI FACTURI "SANMEDICO" S.R.L. IDNO 1003602006 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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 Igg light chain EIA, Free lambda Igg 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	X220V	XEMAtestOvaScreen (Cat. Nr X220V)	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

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:	Initial certification date:	Valid:
53899-2009-AQ-MCW-FINAS	22 May 2009	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, Kellosilankatu 5, 02150 Espoo, Finland

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"MEDICO" S.R.L.
IDNO 1003602008
SOCIETATEA CU RASPUNDERE LIMITATA

ЗАО «ЭКОлаб»142530 Московская обл, г.Электрогорск, ул.Буденного, д.1
e-mail: sekretar@ekolab.ru, Сайт : www.ekolab.ru
Тел: (49643) 3-1374, 3-2311, факс (49643) 3-3143

ИНН: 5035025076, КПП: 503501001
Банк получателя: ПАО Сбербанк России г. Москва
в Орехово-Зуевском ОСБ № 1556/063
р/с 40702810040310124002
к/с 30101810400000000225
БИК 044525225

21.03.2018

АВТОРИЗАЦИЯ ДИСТРИБЬЮТОРА

Закрытое акционерное общество «ЭКОлаб» (Россия, 142530, Московская обл., г.Электрогорск, ул.Буденного, д.1) настоящим подтверждаем , что "SANMEDICO"SRL (ул. Коробчяну 7А, кв. 9, г. Кишинёв, Республика Молдова) является нашим эксклюзивным дистрибьютором в Республике Молдова и осуществляет участие с продукцией ЗАО «ЭКОлаб» в процедурах государственных закупок товаров на территории Республики Молдова, от своего имени ведет переговоры, представляет коммерческие предложения, заключает соответствующие договоры, а также осуществляет поставки указанной продукции на территории Республики Молдова.

Полномочия по настоящему авторизационному письму не могут быть переданы другим лицам.

Настоящее письмо действительно с момента подписания и до 31 декабря 2018г.

Генеральный директор Борисов В.Ю.

Certificat

Certificate

N° 2007/28641.5

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

EKOlab **ZAO «EKOlab»** ЭКОлаб
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

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

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

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

ISO 9001 : 2015

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

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

This certificate is valid from (year/month/day):
Данный сертификат действителен с (год/ месяц/ день) **2016-02-21** until / до **2019-02-21**

Managing director of AFNOR Certification
Генеральный директор AFNOR certification

F.LEBEUGLE

Certificat

Certificate

N° 2007/28642.4

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

EKOlab **ZAO «EKOlab»** ЭКОлаб
ЗАО «ЭКОлаб»

for the following activities:
для следующих областей деятельности:

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

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

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

ISO 13485 : 2003

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

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

This certificate is valid from (year/month/day):
Данный сертификат действителен с (год/ месяц/ день) **2016-02-21** until / до **2019-02-21**

Managing director of AFNOR Certification
Генеральный директор AFNOR certification

F.LEBEUGLE