



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

CERTIFICATE

No. Q1N 16 05 42074 027

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

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

Facility(ies):

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



Certification Mark:



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

**Applied
Standard(s):**

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

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

Report No.: SH1610619

Valid from: 2016-07-15

Valid until: 2019-07-14

Date, 2016-07-08

Stefan Preiß



Page 1 of 1

DAKKS

Deutsche
akkreditierungssysteme
11521-03-101

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

Foresight® TSH EIA Test Kit

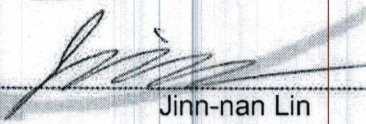
classified as others of the directive 98/79/EC,

**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.

ACON

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

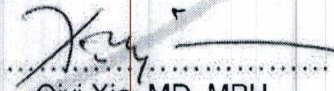
classified as others of the directive 98/79/EC,

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.

ACON

10125 Mesa Rim Road · San Diego, CA 92121 · USA · Tel: (858) 875-8000 · Fax: (858) 875-8098
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

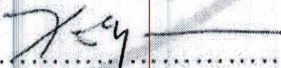
classified as others of the directive 98/79/EC,

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.

ACON

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:

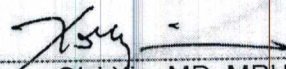
Foresight *H. pylori* IgG EIA Test Kit

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 22 day of Sep, 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



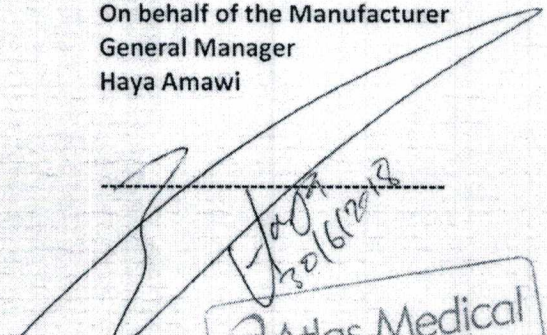
Date: 30/06/2018

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



Handwritten signature of Haya Amawi, dated 30/06/2018, over a stamp that reads "Atlas Medical" and "Medical 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



Handwritten signature

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

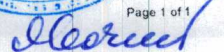
Original Approvals:
ISO 13485 28 February 2009

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



001





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 (Annex I) 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.

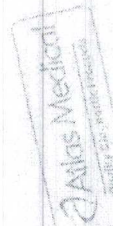
And

intended for In-Vitro Professional use only.

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

Atlas Medical	Issue date December 2011	Date of review 21st of March, 2018	Management approval 	MRXD010F.10 08.02.2011
---------------	-----------------------------	---------------------------------------	-------------------------	---------------------------

Catalogue No	Description	Description
8.00.00	Latex Kits	Calcium Chloride
8.00.01	CRP latex Kits	Fibrinogen Reagent
8.00.02	CRP latex Kits with buffer	Hemoglobin Reagents
8.00.03	ASO latex Kits	Drabkins Reagent, 40x
8.00.04	ASO latex Kits with buffer	Hemoglobin Standard, 15g/dL
8.00.05	RF latex Kits	Sickle Cell Kits
8.00.06	RF latex Kits with buffer	8.02.67 Sickle Cell Kit
8.00.07	hCG latex Kits	8.02.68 Sickle Cell positive & negative control set
8.00.08	IM (Horse Stroma) latex Kits	Urine Reagent Strips
8.00.09	SLE latex Kits	8.03.00 URS 1 Parameter: Glucose
8.00.10	Staphylococcus latex Kits	8.03.01 URS 1 Parameter: Protein
8.00.11	Streptococcus latex Kits	8.03.02 URS 1 Parameter: Ketone
8.00.12	E.Coli latex Kits	8.03.03 URS 2 Parameters: Glucose, Ketone
8.00.13	Rota Virus latex Kits	8.03.04 URS 2 Parameters: Glucose, Protein
8.00.14	D-Dimer latex Kits	8.03.05 URS 2 Parameters: Urobilinogen, Bilirubin (Liver Function Test)
8.00.15	Waaler rose latex Kits	8.03.06 URS 3 Parameters: Protein, pH, Glucose
8.00.16	Brucella Rose Bengal	8.03.07 URS 3 Parameters: Glucose, Protein, Ketone
8.00.17	Salmonella OA Reagent	8.03.15 URS 9 Parameters: Nitrite, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.00.18	Salmonella OB Reagent	8.03.16 URS 10 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose
8.00.19	Salmonella OC Reagent	8.03.17 URS 10 Parameters: Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.00.20	Salmonella OD Reagent	8.03.18 URS 11 Parameters: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose, Ascorbic Acid
8.00.21	Salmonella H8 Reagent	Fertility Rapid Tests
8.01.00	Salmonella HC Reagent	8.04.00 hCG Test Cassette, Urine
8.01.01	Salmonella HD Reagent	8.04.01 hCG Test Cassette, Urine/Serum
8.01.02	Brucella Abortus Reagent	8.04.04 hCG Test Strip, 5.0mm, Urine
8.01.03	Brucella Melitensis Reagent	8.04.05 hCG Test Strip, 3.5mm, Urine
8.01.04	Brucella Melitensis Reagent	8.04.06 hCG Test Strip, 2.5mm, Urine
8.01.05	Proteus OX2 Reagent	8.04.10 hCG Test Strip, 5.0mm, Urine/Serum
8.01.06	Proteus OX19 Reagent	8.04.12 hCG Test Strip, 2.5mm, Urine/Serum
8.01.07	Proteus OXK Reagent	8.04.88 hCG Test Strip, 3.5 mm, Urine/Serum
8.01.08	Brucella Antigen Sets	8.04.90 hCG Test Strip, 2.5 mm, Urine/Serum
8.01.09	Brucella Antigen Kits	8.04.14 LH Test Cassette, Urine
8.01.10	Salmonella Antigen Set (10 Antigens)	8.04.15 LH Test Strip, 3.5mm, Urine
8.01.11	Salmonella Antigen Set (10 Antigens)	8.04.20 Infectious Disease Rapid Test- Antibody Testing
8.01.12	Salmonella Antigen Set (10 Antigens)	H-pylori Antibody Test Cassette
8.01.13	Salmonella Antigen Set (10 Antigens)	Whole Blood/Serum/Plasma
8.01.14	Salmonella Antigen Set (10 Antigens)	
8.01.15	Salmonella Antigen Set (10 Antigens)	
8.01.16	Salmonella Antigen Set (10 Antigens)	
8.01.17	Salmonella Antigen Set (10 Antigens)	
8.01.18	Salmonella Antigen Set (10 Antigens)	
8.01.19	Salmonella Antigen Set (10 Antigens)	
8.01.20	Salmonella Antigen Set (10 Antigens)	
8.02.40	PT Calcium Rabbit Brain Thromboplastin, liquid	
8.02.41	APTT (PTT) Micronised Silica Platelet Substitute, Liquid	
8.02.60	Normal Coagulation Control	
8.02.61	Abnormal Coagulation Control	
8.02.44	PT Kit	
8.02.45	APTT (PTT) Kit	



Atlas Medical

Catalogue No	Description	Description
8.04.21	H.pylori Antibody Test Cassette, S/P	Cocaine Test Cassette, Urine
8.04.22	H.pylori Antibody Test Strip, S/P	Cocaine Test Strip, Urine
8.04.41	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma	Methamphetamine Test Cassette, Urine
8.04.42	Syphilis Antibody Test Cassette, S/P	Methamphetamine Test Strip, Urine
8.04.43	Syphilis Antibody Test Strip, S/P	Methadone Test Cassette, Urine
8.04.44	Dengue IgM/IgG Test Cassette WB/S/P	Methadone Test Strip, Urine
8.04.23	Infectious Disease Rapid Test - Antigen Testing	Phencyclidine Test Cassette, Urine
8.04.24	H.pylori Antigen Test Cassette, Stool Sample	Phencyclidine Test Strip, Urine
8.04.24	H.pylori Antigen Test Strip, 3.5mm, Stool Sample	Tricyclic Anti-Depressants Test Cassette, Urine
8.04.69	Rotavirus Antigen Test Cassette, Stool Sample	Tricyclic Anti-Depressants Test Strip, Urine
8.04.70	Rotavirus Antigen Test Strip, 3.5mm, Stool Sample	Buprenorphine Test Cassette, Urine
8.04.71	Adenovirus Antigen Test Cassette, Stool Sample	Buprenorphine Test Strip, Urine
8.04.72	Adenovirus Antigen Test Strip, 3.5mm, Stool Sample	Methylenedioxyamphetamine (MDMA) Ecstasy Test Cassette, Urine
8.04.73	Rota-Adeno Antigens Combobest Cassette, Stool Sample	Methylenedioxyamphetamine (MDMA) Ecstasy Test Strip, Urine
8.04.74	Rota-Adeno Antigens Combobest Strip, 3.5mm, Stool Sample	Opiates Test Cassette, Urine
8.16.42	Rota Virus Positive Control	Opiates Test Strip, Urine
8.16.43	Influenza A+B Test Cassette, Nasal Sample	Tramadol Test Cassette, Urine
8.04.96	Influenza A+B Test Strip, Nasal Sample	Tramadol Test Strip, Urine
8.04.97	Astro Virus Test Cassette, Nasal Sample, Buffer to be supplied in Extraction Tube	Tramadol Test Cassette, Urine
8.04.98	Astro Virus Test Strip, Stool Sample, Buffer to be supplied in Extraction Tube	Cotinine Test Cassette, Urine
8.16.20	RSV Test Cassette, Swab Sample	Cotinine Test Strip, Urine
8.16.22	RSV Test Strip, Swab Sample	Dolantin Test Cassette, Urine
8.16.31	Giardia test Cassette, stool sample	Dolantin Test Strip, Urine
8.16.30	Giardia test strip, stool sample	Oxycodone Test Cassette, Urine
8.04.38	Cancer Markers Rapid Tests	Oxycodone Test Strip, Urine
8.04.85	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample	Ketamine Test Cassette, Urine
8.04.45	Fecal Occult Blood Test (FOB) Test Strip	Ketamine Test Strip, Urine
8.04.48	Troponin I Test Cassette, WB/S/P	Proxiphen Test Cassette, Urine
8.04.48	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin)	EDDP Test Cassette, Urine
8.04.49	Morphine Test Cassette, Urine	EDDP Test Strip, Urine
8.04.50	Morphine Test Strip, Urine	DOA Panel: 2 Drugs, Urine
8.04.51	Marijuana (THC) Test Cassette, Urine	DOA Panel: 3 Drugs, Urine
8.04.52	Marijuana (THC) Test Strip, Urine	DOA Panel: 4 Drugs, Urine
8.04.53	Amphetamine Test Cassette, Urine	DOA Panel: 5 Drugs, Urine
8.04.54	Amphetamine Test Strip, Urine	DOA Panel: 6 Drugs, Urine
8.04.55	Barbiturates Test Cassette, Urine	DOA Panel: 7 Drugs, Urine
8.04.56	Barbiturates Test Strip, Urine	DOA Panel: 8 Drugs, Urine
8.04.57	Benzodiazepines Test Cassette, Urine	DOA Panel: 9 Drugs, Urine
8.04.58	Benzodiazepines Test Strip, Urine	DOA Panel: 10 Drugs, Urine
8.05.03	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)	DOA Panel: 11 Drugs, Urine
		DOA Panel: 12 Drugs, Urine

Atlas Medical

Catalogue No	Description	Description
8.05.04	Alkaline Phosphatase Kinetic, DGKC	Alkaline Phosphatase Kinetic, DGKC
8.05.12	Bilirubin Total (DMISO Method)	Bilirubin Total (DMISO Method)
8.05.07	Bilirubin Total & Direct (DMISO Method)	Bilirubin Total & Direct (DMISO Method)
8.05.08	Calcium Arsenazo III	Calcium Arsenazo III
8.05.09	Calcium O-Cresolphthalein	Calcium O-Cresolphthalein
8.05.10	Chloride Thiocyanate Colorimetric	Chloride Thiocyanate Colorimetric
8.05.11	Cholesterol Liquid (CHOD-POD)	Cholesterol Liquid (CHOD-POD)
8.05.26	HDL Cholesterol Precipitating Reagent	HDL Cholesterol Precipitating Reagent
8.05.51	HDL Cholesterol, Enzymatic Colorimetric Direct Method	HDL Cholesterol, Enzymatic Colorimetric Direct Method
8.05.12	CK-MB Kinetic (Tablets)	CK-MB Kinetic (Tablets)
8.05.13	CK-MB Kinetic (Liquid)	CK-MB Kinetic (Liquid)
8.05.14	CK-NAC Kinetic (Tablets)	CK-NAC Kinetic (Tablets)
8.05.15	CK-NAC Kinetic (Liquid)	CK-NAC Kinetic (Liquid)
8.05.16	Creatinine Jaffe Color-Kinetic	Creatinine Jaffe Color-Kinetic
8.05.17	Glucose GOD-POD (Liquid)	Glucose GOD-POD (Liquid)
8.05.18	GOT (AST) IFCC Kinetic (Tablets)	GOT (AST) IFCC Kinetic (Tablets)
8.05.19	GOT (AST) IFCC Kinetic (Liquid)	GOT (AST) IFCC Kinetic (Liquid)
8.05.20	GOT (AST) Reitman-Frankel Colorimetric	GOT (AST) Reitman-Frankel Colorimetric
8.05.21	GPT (ALT) IFCC Kinetic (Tablets)	GPT (ALT) IFCC Kinetic (Tablets)
8.05.22	GPT (ALT) IFCC Kinetic (Liquid)	GPT (ALT) IFCC Kinetic (Liquid)
8.05.23	GPT (ALT) Reitman-Frankel Colorimetric	GPT (ALT) Reitman-Frankel Colorimetric
8.05.24	Gamma GT Kinetic, Carboxy Substrate (Tablets)	Gamma GT Kinetic, Carboxy Substrate (Tablets)
8.05.25	Gamma GT Kinetic, Carboxy Substrate (Liquid)	Gamma GT Kinetic, Carboxy Substrate (Liquid)
8.05.27	Iron Ferrozine Colorimetric	Iron Ferrozine Colorimetric
8.05.28	LHD IFCC Kinetic (Tablets)	LHD IFCC Kinetic (Tablets)
8.05.29	LDH IFCC Kinetic (Liquid)	LDH IFCC Kinetic (Liquid)
8.05.30	Lipase Kinetic (Liquid)	Lipase Kinetic (Liquid)
8.05.31	Magnesium Calmagite Colorimetric	Magnesium Calmagite Colorimetric
8.05.32	Phosphorus Phosphomolybdate UV	Phosphorus Phosphomolybdate UV
8.05.33	Potassium Colorimetric	Potassium Colorimetric
8.05.34	Sodium Colorimetric	Sodium Colorimetric
8.05.35	TIBC (Total Iron Binding Capacity)	TIBC (Total Iron Binding Capacity)
8.05.36	Total Lipids Phosphovanillinine Colorimetric	Total Lipids Phosphovanillinine Colorimetric
8.05.37	Total Protein Biuret Colorimetric	Total Protein Biuret Colorimetric
8.05.38	Total Protein in CSF	Total Protein in CSF
8.05.39	Triglycerides GPO-POD Colorimetric	Triglycerides GPO-POD Colorimetric
8.05.40	Urea Urease-GLDH Kinetic (UV)	Urea Urease-GLDH Kinetic (UV)
8.05.41	Urea Berthelot Colorimetric	Urea Berthelot Colorimetric
8.05.42	Uric Acid Uricase-PAP Colorimetric	Uric Acid Uricase-PAP Colorimetric
8.05.71	Uric Acid Uricase-PAP Colorimetric (Mono Reagents)	Uric Acid Uricase-PAP Colorimetric (Mono Reagents)



Handwritten signature and stamp: J. St. P. Q.



XEMA

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



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 (MPDG) § 5,25,29,30

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Richtlinie 98/79/EG Artikel 10 über In-Vitro-Diagnostika und Medizinproduktegesetz (MPDG) §§ 5,25,29,30

Manufacturer:
Hersteller
Xema Co., Ltd.
bl.d.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 point 6, 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-Registrierungsnummer
See annex to the Certificate
Siehe Anhang zum Zertifikat

Date of issue: 2016-12-31
Das Ausstellungsdatum

Valid to: 2019-12-31
Gültig bis

Represented in the EC by Polmed.de
Steinacker 5, 73773 Achwald, Germany
email: info@polmed.de
tel: +49 711 52953279



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	Product registration number Registrierungsnummer	DIMDI
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	Gladin Igg EIA Cat. Nr. K180; Gladin Iga EIA Cat. Nr. K181; Desamidated Gladin Iga EIA, Desamidated Gladin 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 K202	TSH EIA Cat. Nr. K201; TSH Plus EIA Cat. Nr. K202A	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)	K209S K2095	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.	TRIODOTHYRONINE	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 TRIGLYCERID-HORMONE	K213	Free TG EIA Cat. Nr. K213	DE/CA37/IVD/13/26	
20.	FREE THYROXINE	K214	Free T4 EIA Cat. Nr. K214	DE/CA37/IVD/13/25	
21.	DEHYDRO-EPANDROSTERONE 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/13/23	
23.	CANCER ANTIGEN 125	K222	CA 125 EIA Cat. Nr. K222	DE/CA37/IVD/13/22	
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.

Valid with the Extract from the database www.dimdi.de (German Institute for Medical Documentation)
Gültig mit der Auszug aus der Datenbank www.dimdi.de (Deutsches Institut für Medizinische Dokumentation)



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	DIMI Product registration number Registrierungsnummer
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. Nr. K226	DE/CA37/IVD/13/18
28. OTHER CANCER ANTIGENS	K227 K228	MUC11 M22 EIA Cat. Nr. K227; MUC11 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. HUMAN CHRONIC 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	Albomun 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	Tropoin T 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 K275 K277	IgG2 EIA Cat. Nr. K272; IgG4 EIA Cat. Nr. K274; Total IgA EIA Cat. Nr. K275; Total IgM EIA Cat. Nr. K277	DE/CA37/IVD/13/8 DE/CA37/IVD/13/7 DE/CA37/IVD/13/6
38. IMMUNOGLOBULIN A	KQ13	AutoQon A1 immunosay control set Cat. Nr. KQ13;	
39. IMMUNOGLOBULIN M	KQ14	AutoQon ANA/FNA immunosay control set Cat. Nr. KQ14;	
40. RHEUMATOID/AUTIMMUNE CONTROLS	KQ15	AutoQon ACL immunosay control set Cat. Nr. KQ15	DE/CA37/IVD/13/5
41. HORMONE CONTROLS	KQ21	HomoQon immunosay control set Cat. Nr. KQ21	DE/CA37/IVD/13/4
42. TUMOUR MARKER CONTROLS	KQ22	OmaQon immunosay 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	K244	TSH-Nest-EIA	DE/CA37/IVD/13/47
46. ESTRON	K238	Free Estriol EIA	DE/CA37/IVD/13/48
47. IMMUNOGLOBULIN E - MONOEST/MONORESULT - MULTI-AG	K2005	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 RT 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.

Valid with the Extract from the database www.dlmed.de (German Institute for Medical Certification)
Gilt nur mit Auszug aus der Datenbank www.dlmed.de (Deutsches Institut für Medizinische Zertifizierung)

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	DIMI Product registration number Registrierungsnummer
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 1/2 Igg EIA (Cat. Nr. K104)	DE/CA37/IVD/13/67
53. HSV IGM	K104M	HSV 1/2 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 LAMBLLIA	K171	Giardia lamblia Total Ab EIA (Cat. Nr. K171)	DE/CA37/IVD/13/57
63. OTHER TUMOUR MARKER RAPID TESTS	X220V	XEMAgestOncScreen (Cat. Nr. X220V)	DE/CA37/IVD/13/56
64. OTHER TUMOUR MARKER RAPID TESTS	K222	XEMAgestCA25 (Cat. Nr. X222)	DE/CA37/IVD/13/55
65. OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAgestHER (Cat. Nr. X239)	DE/CA37/IVD/13/54
66. IMMUNOGLOBULIN A IGA	K276	SECRETORY Iga (Cat. Nr. 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/13/68E

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
Stienacker 5, 73773 Alchwald, Germany
email: info@polmed.de
tel: +49 711 52853279



Valid with the Extract from the database www.dlmed.de (German Institute for Medical Certification)
Gilt nur mit Auszug aus der Datenbank www.dlmed.de (Deutsches Institut für Medizinische Zertifizierung)

MANAGEMENT SYSTEM CERTIFICATE

Certificate No: 53899-2009-AQ-MCW-FINAS
Place and date: Moscow, 14 March 2018

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.

Valid:
14 March 2018 - 28 February 2019

Initial certification date:
22 May 2009

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

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

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



S. Groobme
Serguei Groubine
Management Representative

Lack of sufficient of conditions as set out in the Certification Agreement may render this Certificate invalid. This Certificate has been digitally signed. See www.dnvgl.com/digitalcertificates for more info.
ACCREDITED UNIT: DNV GL BUSINESS ASSURANCE FINLAND OY AB, KARLARBORG 5, 02150 Espoo, Finland. TEL: +359 10 39 4200. www.dnvgl.com

Lack of sufficient of conditions as set out in the Certification Agreement may render this Certificate invalid. This Certificate has been digitally signed. See www.dnvgl.com/digitalcertificates for more info.
ACCREDITED UNIT: DNV GL BUSINESS ASSURANCE FINLAND OY AB, KARLARBORG 5, 02150 Espoo, Finland. TEL: +359 10 39 4200. www.dnvgl.com

