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
...edical Disposable 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

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1...2008154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

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

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 (Annexl) 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	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

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

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Catalouge No	Description
8.04.21	H.pylori Antibody Test Cassette, S/P
8.04.22	H.pylori Antibody Test Strip, S/P
8.04.41	Syphilis Antibody Test Cassette, Whole Blood/Serum/Plasma
8.04.42	Syphilis Antibody Test Cassette, S/P
8.04.43	Syphilis Antibody Test Strip, S/P
8.04.44	Dengue IgM/IgG Test Cassette WB/S/P
Infectious Disease Rapid Test - Antigen Testing	
8.04.23	H.pylori Antigen Test Cassette, Stool Sample
8.04.24	H.pylori Antigen Test Strip, 3.5mm, Stool Sample
8.04.69	Rotavirus Antigen Test Cassette, Stool Sample
8.04.70	Rotavirus Antigen Test Strip, 3.5mm, Stool Sample
8.04.71	Adenovirus Antigen Test Cassette, Stool Sample
8.04.72	Adenovirus Antigen Test Strip, 3.5mm, Stool Sample
8.04.73	Rota-Adeno Antigens Combotest Cassette, Stool Sample
8.04.74	Rota-Adeno Antigens Combotest Strip, 3.5mm, Stool Sample
8.16.42	Rota Virus Positive Control
8.16.43	Adeno Virus Positive Control
8.04.86	Influenza A+B Test Cassette, Nasal
8.04.96	Influenza A+B Test Strip, Nasal Sample
8.04.97	Astro Virus Test Cassette, Nasal Sample, Buffer to be supplied in Extraction Tube
8.04.98	Astro VirusTest Strip, Stool Sample, Buffer to be supplied in Extraction Tube
8.16.20	RSV Test Cassette, Swab Sample
8.16.22	RSV Test Strip, Swab Sample
8.16.31	Giardia test Cassette,stool sample
8.16.30	Giardia test strip,stool sample
Cancer Markers Rapid Tests	
8.04.38	Fecal Occult Blood Test (FOB) Test Cassette, Stool Sample
8.04.85	Fecal Occult Blood Test (FOB) Test Strip
Cardiac Markers Rapid Tests	
8.04.45	Troponin I Test Cassette, WB/S/P
8.04.48	Cardiac Triple Test Cassette (Troponin I, CK-MB, Myoglobin)
DOA Rapid Tests	
8.04.49	Morphine Test Cassette, Urine
8.04.50	Morphine Test Strip, Urine
8.04.51	Marijuana (THC) Test Cassette,Urine
8.04.52	Marijuana (THC) Test Strip, Urine
8.04.53	Amphetamine Test Cassette, Urine
8.04.54	Amphetamine Test Strip, Urine
8.04.55	Barbiturates Test Cassette, Urine
8.04.56	Barbiturates Test Strip, Urine
8.04.57	Benzodiazepines Test Cassette, Urine
8.04.58	Benzodiazepines Test Strip, Urine

Catalouge No	Description
8.05.03	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)

Catalouge No	Description
8.04.59	Cocaine Test Cassette, Urine
8.04.60	Cocaine Test Strip, Urine
8.04.61	Methamphetamine Test Cassette, Urine
8.04.62	Methamphetamine Test Strip, Urine
8.04.63	Methadone Test Cassette, Urine
8.04.64	Methadone Test Strip, Urine
8.04.65	Phencyclidine Test Cassette, Urine
8.04.66	Phencyclidine Test Strip, Urine
8.04.67	Tricyclic Anti-Depressants Test Cassette, Urine
8.04.68	Tricyclic Anti-Depressants Test Strip, Urine
8.04.99	Buprenorphine Test Cassette, Urine
8.16.23	Buprenorphine Test Strip, Urine
8.16.15	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Cassette, Urine
8.16.05	Methylenedioxymethamphetamine (MDMA) Ecstasy Test Strip, Urine
8.16.06	Opiates Test Cassette, Urine
8.16.07	Opiates Test Strip, Urine
8.16.68	Tramadol Test Cassette, Urine
8.16.44	Tramadol Test Strip, Urine
8.16.58	Cotinine Test Cassette, Urine
8.16.59	Cotinine Test Strip, Urine
8.16.60	Dolantin Test Cassette, Urine
8.16.61	Dolantin Test Strip, Urine
8.16.62	Oxycodone Test Cassette, Urine
8.16.63	Oxycodone Test Strip, Urine
8.16.64	Ketamine Test Cassette, Urine
8.16.65	Ketamine Test Strip, Urine
8.16.66	Proxyphene Test Cassette, Urine
8.16.67	Proxyphene Test Strip, Urine
8.16.69	EDDP Test Cassette, Urine
8.16.70	EDDP Test Strip, Urine
8.04.93	DOA Panel: 2 Drugs,Urine
8.04.94	DOA Panel: 3 Drugs,Urine
8.04.95	DOA Panel: 4 Drugs,Urine
8.04.79	DOA Panel: 5 Drugs,Urine
8.04.80	DOA Panel: 6 Drugs,Urine
8.04.81	DOA Panel: 7 Drugs,Urine
8.04.82	DOA Panel: 8 Drugs,Urine
8.04.83	DOA Panel: 9 Drugs,Urine
8.04.84	DOA Panel: 10 Drugs,Urine
8.16.03	DOA Panel: 11 Drugs,Urine
8.16.04	DOA Panel: 12 Drugs,Urine
Kidney Function Rapid Tests	
8.16.52	Microalbumin Test Cassette
Clinical Chemistry Kits	
8.05.00	Albumin Bromocresol Green
8.05.01	Amylase
8.05.02	Acid Phosphatase Kinetic, Hilmann Method (Tablets)
8.05.02	Acid Phosphatase Kinetic, Hilmann Method (Tablets)

8.05.04	Alkaline Phosphatase Kinetic, DGKC
8.05.72	Alkaline Phosphatase Colorimetric Method
8.05.05	Bilirubin Total (DMSO Method)
8.05.07	Bilirubin Total & Direct (DMSO Method)
8.05.08	Calcium Arsenazo III
8.05.09	Calcium O-Cresophthalein
8.05.10	Chloride Thyocianate Colorimetric
8.05.11	Cholesterol Liquid (CHOD-POD)
8.05.26	HDL Cholesterol Precipitating Reagent
8.05.51	HDL Choelsterol, Enzymatic Colorimetric Direct Method
8.05.12	CK-MB Kinetic (Tablets)
8.05.13	CK-MB Kinetic (Liquid)
8.05.14	CK-NAC Kinetic (Tablets)
8.05.15	CK-NAC Kinetic (Liquid)
8.05.16	Creatinine Jaffe Coler-Kinetic
8.05.17	Glucose GOD-POD (Liquid)
8.05.18	GOT (AST) IFCC Kinetic (Tablets)
8.05.19	GOT (AST) IFCC Kinetic (Liquid)
8.05.20	GOT (AST) Reitman-Frankel Colorimetric
8.05.21	GPT (ALT) IFCC Kinetic (Tablets)
8.05.22	GPT (ALT) IFCC Kinetic (Liquid)
8.05.23	GPT (ALT) Reitman-Frankel Colorimetric
8.05.24	Gamme GT Kinetic, Carboxy Substrate (Tablets)
8.05.25	Gamme GT Kinetic, Carboxy Substrate (Liquid)
8.05.27	Iron Ferrozine Colorimetric
8.05.28	LHD IFCC Kinetic (Tablets)
8.05.29	LDH IFCC Kinetic (Liquid)
8.05.30	Lipase Kinetic (Liquid)
8.05.31	Magnesium Calmagite Colorimetric
8.05.32	Phosphorus Phosphomolybdate UV
8.05.33	Potassium Colorimetric
8.05.34	Sodium Colorimetric
8.05.35	TIBC (Total Iron Binding Capacity)
8.05.36	Total Lipids Phosphovalnilline Colorimetric
8.05.37	Total Protein Biuret Colorimetric
8.05.38	Total Protein in CSF
8.05.39	Triglycerides GPO-POD Colorimetric
8.05.40	Urea Urease-GLDH Kinetic (UV)
8.05.41	Urea Berthelot Colorimetric
8.05.42	Uric Acid Uricase-PAP Colorimetric
8.05.71	Uric Acid Uricase-PAP Colorimetric (Mono Reagents)

Catalouge No	Description
8.05.43	Pathological Control for Clinical Chemistry
8.05.44	Normal Control for Clinical Chemistry, Lyophilized, Human Source
Hormone Elisa Kits	
8.10.01	hCG Elisa Kit
8.10.03	FSH Elisa Kit
8.10.04	LH Elisa Kit
8.10.05	Prolactin Elisa Kit
8.12.00	T3 Elisa Kit
8.12.01	T4 Elisa Kit
8.12.02	TSH Elisa Kit
8.12.03	Free T4 Elisa Kit
8.12.04	Free T3 Elisa Kit
Alcohol Tests	
8.25.01	Saliva Alcohol Test Strip
8.25.02	Breath Alcohol Test (0.02%)
8.25.03	Breath Alcohol Test (0.05%)
8.25.04	Breath Alcohol Test (0.08%)
Home Test (OTC)	
70170001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70180001	Atlas Home Pregnancy Test Strip (With Handle), 1 Test/Box
70171001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70172001	Atlas Home Pregnancy Test Cassette, 1 Test/Box
70174001	Atlas Home Ovulation Test Cassette, 5 Tests/Box
70175001	Atlas Home Ovulation Test Midstream, 3 Tests/Box
70177001	Atlas Home Menopause Test Cassette, 1 Test/Box
70178001	Atlas Home Menopause Test Midstream, 1 Test/Box
70004001	Atlas Home Diabetes Test, 2Tests/Box
70021001	Atlas Home Urinary Tract Infection Test, 2 Tests/Box
70022001	Atlas Home Kidney Function Test, 2 Tests/Box
70023001	Atlas Home Liver Function Test, 2 Tests/Box

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Atlas Medical

Catalouge No	Description
Antibiotic Sensitivity Mono Discs	
8.39.01	AMIKACIN (30 µg) – AK (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.02	AMOXICILLIN (10 µg) – AX (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.03	AMOXICILLIN /CLAVULANIC ACID (20 µg+ 10 µg) - AC (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.04	AMPICILLIN (10 µg)–AP (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.05	AMPICILLIN /SULBACTAM (10 µg -10 µg – AS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.06	AZITHROMYCIN (15 µg)–AZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.07	AZTREONAM (30 µg)–AT (5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.08	CEFACLOR (30 µg) - CG (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.09	CEFADROXIL (30 µg) - CD(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.10	CEFAZOLIN (30 µg) - CF (5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.11	CEFDINIR (5µg) - CN(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.12	CEFIXIME (5 µg)-FX (5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.13	CEFOPERAZONE (75 µg)-PZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.14	CEFOPERAZONE / SULBACTUM (75 µg 30 µg) - CS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.15	CEFOTAXIME (30 µg)- CX (5 Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.16	CEFPIROME (30 µg) - CE (5 Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.17	CEFPODOXIME (10µg)–CO(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.18	CEFPROZIL (30 µg) - FP (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.19	CEFTAZIDIME (30 µg)–CZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.20	CEFTIZOXIME (30 µg) - FO(5 Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.21	CEFTRIOXONE (30 µg) - FR(5 Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.22	CEFUROXIME (30 µg)-CR(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.23	CEPHALEXIN (30 µg)-CP(5Cartridgex50 Discs with Cartridge Applicator per Box)

Catalouge No	Description
8.39.24	CEPHALORIDINE (30 µg)-CH(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.25	CEPHALOTHIN (30 µg) -CA(5Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.26	CHLORAMPHENICOL (30 µg)-CK(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.27	CIPROFLOXACIN (5 µg) - CL (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.28	CLARITHROMYCIN (15 µg) - CL (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.29	CLINDAMYCIN (2 µg)-CM(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.30	CLOXACILLIN (5 µg) - CV (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.31	CO-TRIMOXAZOLE (25 µg)-CT(5Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.32	DOXYCYCLINE (30 µg) - DO (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.33	ERYTHROMYCIN (15 µg) - ER (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.34	FURAZOLIDONE (100 µg)-FZ(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.35	GATIFLOXACIN (5 µg) - GF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.36	GENTAMYCIN (10 µg) - GM (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.37	IMIPENEM / CILASTATIN (10 µg + 10 µg) - IS (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.38	KANAMYCIN (30 µg)- KA(5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.39	LEVOFOLXACIN (5 µg) - LV (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.40	LINCOMYCIN (15 µg) - LN (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.41	LINEZOLID (30 µg) - LI (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.42	LOMEFLOXACIN (10 µg) - LF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.43	MEROPENEM (10 µg)-MR (5 Cartridge x 50 Discs with Cartridge Applicator per Box)

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Catalouge No	Description
8.39.44	MINOCYCLINE(30µg)-MN(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.45	MOXIFLOXACIN (5µg)-MF(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.46	NALIDIXIC ACID (30 µg)-NA(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.47	NITROFURANTOIN (300 µg) - FU (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.48	NORFLOXACIN (10µg)-NF(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.49	OFLOXACIN (5 µg) - OF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.50	PEFLOXACIN (5 µg) – PF (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.51	PENICILLIN–G(10 IU)–PG(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.52	PIPERACILLIN(100µg)–PC(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.53	PIPERACILLIN / TAZOBACTAM (100 µg + 10 µg) - PT (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.54	RIFAMPIN (5 µg) – RN (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.55	ROXITHROMYCIN (30µg)–RO(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.56	SPARFLOXACIN(5µg)–SP(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.57	STREPTOMYCIN (10 µg)–ST(5Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.58	SULPHADIAZINE (300µg)–SD (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.59	TEICOPLANIN (30µg)–TC(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.60	TETRACYCLINE(30µg)–TE(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.61	TICARCILLIN / CLAVULANIC ACID (75 µg + 2.5 µg)-TC (5 Cartridge x 50 Discs with Cartridge Applicator per Box)
8.39.62	TOBRAMYCIN (10µg)–TO(5 Cartridgex 50 Discs with Cartridge Applicator per Box)
8.39.63	TRIMETHOPRIM(5µg)–TR(5Cartridgex50 Discs with Cartridge Applicator per Box)
8.39.63	TRIMETHOPRIM(5µg)–TR(5Cartridgex50 Discs with Cartridge Applicator per Box)
Glucose Monitoring	
8.16.73	Blood Glucose Visual Test Strip
8.40.00	HbA1c Direct Enzymatic Colorimetric Kit

Atlas Medical

Catalouge No	Description
Blood Culture	
8.38.00	Blood Culture Bottles, Pediatric Size
8.38.01	Blood Culture Bottles, Adult Size
Syphilis Kits	
8.00.18	RPR Carbon Antigen (Coarse Grain) Kit
8.00.18.1	RPR Carbon Antigen (Fine Grain) Kit
8.00.19	TPHA Kit
8.00.20	VDRL Kit
Stains for Histology & Microbiology	
8.15.017	Carbol Fuchsin (Gram)
8.15.019	Carbol Fuchsin (Ziehl-Neelsen)
8.15.032	Crystal Violet (for Gram Stain)
8.15.037	Eosin Y (1% Aqueous)
8.15.038	Eosin Y (5% Aqueous)
8.15.039	Eosin Y (1% Alcoholic)
8.15.041	Field Stain (Solution A)
8.15.042	Field Stain (Solution B)
8.15.047	Giemsa Stain (Modified-Glycerol/ Methanol)
8.15.049	Gram's Iodine
8.15.051	Gram's Decolouriser
8.15.059	Haematoxylin Harris (no Acetic Acid)
8.15.060	Haematoxylin Harris (with Acetic Acid)
8.15.069	Leishman Stain
8.15.074	Lugol's Iodine,
8.15.076	Malachite Green (Aqueous)
8.15.078	May Grunwald Stain (Modified)
8.15.105	New Methylene Blue for Reticulocytes
8.15.110	Papanicolaou Stain EA35
8.15.111	Papanicolaou Stain EA36
8.15.112	Papanicolaou Stain EA65
8.15.114	Papanicolaou Stain EA50
8.15.115	Papanicolaou Stain OG6
8.15.126	Safranin (1% Aqueous)
8.15.143	Wright's Stain (Modified)
8.15.144	ZN Decolouriser
8.15.017	Carbol Fuchsin (Gram)
8.15.019	Carbol Fuchsin (Ziehl-Neelsen)
8.15.032	Crystal Violet (for Gram Stain)
8.15.037	Eosin Y (1% Aqueous)
8.15.038	Eosin Y (5% Aqueous)
8.15.039	Eosin Y (1% Alcoholic)
8.17.003	Periodic Acid Schiff (PAS) Stain Kit
8.17.004	Iron Stain Kit- Perl
8.17.009	Gram Stain Pack
8.17.010	Cold ZN- Kinyoun Stain Pack
8.17.011	ZN Pack Standard
8.17.015	Diff 3 stain pack
8.17.015	Papanicolau stain kit (EA35, EA65, OG6, EA50)

REPUBLICA MOLDOVA MUNICIPIUL CHISINAU PENTRU CONTRACTE SI FACTURI "SANMEDICO" S.R.L. IDNO 1008008154 SOCIETATEA CU RASPUNDERE LIMITATA

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

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PENTRU CONTRACTE SI ACHIZITII PUBLICE
"SANMEDICO"
IDNO 1003600[illegible]154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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:

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 CRT2 / 10 13

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.[illegible]

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.[illegible]

Подпись: _____

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

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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-EI-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015

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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