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

30/6/18

Atlas Medical
...ottle 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 FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602006154
SOCIETATE 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. CHISINAU "SANMEDICO" PENTRU CONTRACTE SI FACTURI

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
Quality Risk Management

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

Atlas Medical
Quality Risk Management

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

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 Phosphovainilline 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, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602008154
SUNTETATEA CU RASPUNDERE LIMITATA

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

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

Date: February 13, 2018

LETTER OF AUTHORIZATION

To whom it may concern:

We, LumiQuick Diagnostics Inc. having a registered office at 2946 Scott Blvd, Santa Clara, CA 95054, USA, assign Sanmedico SRL having a registered office at str. A. Corobceanu 7A, apt. 9, Chişinău MD-2012, Moldova , as authorized representative in correspondence with the conditions of directive 98/79/EEC.

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

This authorization letter is valid until February 28, 2020.

Best regards,

Charles Yu
President

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

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

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

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

Declaration of Conformity

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

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

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

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

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

COMPANY REPRESENTATIVE: Jeff Wang

TITLE: Quality Systems Manager **SIGNATURE:**

DATE: 28/04/2017

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

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

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

Holds Certificate No: **FM 574919**

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

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

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

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

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

...making excellence a habit.™

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

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: _____

СЕРТИФИКАТ

Настоящий сертификат удостоверяет, что Система Менеджмента Качества организации

ООО Фирма «Технология-Стандарт»

656037, Россия, Барнаул, проспект Калинина 116 / 95

соответствует требованиям стандарта систем менеджмента качества

EN ISO 13485:2012

(ISO 13485:2003 + Cor 1:2009)

в области:

РАЗРАБОТКА, ПРОИЗВОДСТВО И РЕАЛИЗАЦИЯ ДИАГНОСТИЧЕСКИХ НАБОРОВ И РЕАГЕНТОВ ДЛЯ IN VITRO ДИАГНОСТИКИ СИСТЕМЫ ГЕМОСТАЗА

Сертификат N°: M-0379/16 **Дата выставления: 05.08.2016** **Дата регистрации: 05.08.2016**

Этот сертификат, при условии постоянного успешного функционирования Системы Менеджмента Качества организации, действителен до: **01.03.2019**. По вопросам действия сертификата звоните по тел.: +421 (0)2 5831 8343.

Dr. Katarína Srdošová
Руководитель Органа по сертификации

КОПИЯ ВЕРНА
ООО фирма "Технология-Стандарт"
директор А.П. Момот

Выставил: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Словацкая Республика

SNAS Reg. No. 305/Q-054

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

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

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«ChromoTech-Antithrombin» The kit of reagents for the determination of antithrombin concentration in blood plasma	192	Low	13 02 06 02/ 33156	09.02.2015
«Plasma-control» The kit of control blood plasma for the study of haemostasis	400	Low	13 02 50 02/ 30590	09.02.2015
«Thrombo-test» The kit of reagents for the determination of thrombin time	151, 609, 610	Low	13 02 01 03/ 30540	09.02.2015
«Tech-Factor VIII-test» The kit of reagents for the determination of factor VIII activity in blood plasma	274	Low	13 02 02 07/ 30547	09.02.2015
«PARUS-test» The kit of reagents for the determination of disorders in protein C system	164	Low	13 02 06 08/ 30588	09.02.2015
«APTT-El-test» The kit of reagents for the determination of activated partial thromboplastin time	649, 652	Low	13 02 01 02/ 32392	09.02.2015
«Soluble thromboplastin with calcium» A reagent for determination of prothrombin time	643, 638	Low	13 02 01 01/ 30539	09.02.2015
«Thrombin» A reagent for the study of haemostasis	323, 017	Low	13 02 01 03/ 30540	09.02.2015

Device name	Type/ model/ref number	Risk class	Code:EMDS/GMDN [1]	First date of CE-compliance
«Tech-Factor IX-test» The kit of reagents for the determination of factor IX activity in blood plasma	679	Low	13 02 02 08/ 30548	09.02.2015
«RNP-plasma» Reference normal pooled plasma	012	Low	13 02 50 02/ 30590	09.02.2015
«Pathoplasma» Pathologic plasma	013	Low	13 02 50 02/ 32394	09.02.2015
«Techplastin-test (K)» The kit of reagents for the determination of prothrombin time, prothrombin ratio and INR in blood	144	Low	13 02 01 01/ 30539	09.02.2015
«Tech-Antithrombin-test» The kit of reagents for the determination of antithrombin III activity	688	Low	13 02 06 02/ 33156	09.02.2015
«Lupus-test» The kit of reagents for the determination of anticoagulants of lupus type	011	Low	13 02 06 07/ 30587	09.02.2015
«Express-Lupus-test» The kit of reagents for the determination of lupus anticoagulant	193	Low	13 02 06 07/ 30587	09.02.2015
«Fibrinolysis-test» The kit of reagents for the study of XIIa-kininogenase-dependent, spontaneous and induced euglobulin fibrinolysis	009	Low	13 02 05 90/ 0	09.02.2015

REPUBLICA MOLDOVA, mun. CHISINAU
PENTRU CONTRACTE SI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602006154
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

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

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

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

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 17 08 80997 017

Manufacturer: **ACON Laboratories, Inc.**
10125 Mesa Rim Road
San Diego CA 92121
USA

EC-Representative: **Medical Device Safety Service GmbH**
Schiffgraben 41
30175 Hannover
GERMANY

Product Category(ies): **In Vitro diagnostics for the detection of human infections and tumor markers, blood glucose measuring self-testing systems, self-testing devices for clinical chemistry, hematology and pregnancy**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17743EXT01

Valid from: 2017-09-13
Valid until: 2022-09-12

Date, 2017-08-30

Stefan Preiß

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

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

Product Service

EC Certificate
Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)
No. V1 17 08 80997 017

Model(s): **For Detail Models see attachment**

Facility(ies): **ACON Laboratories, Inc.**
10125 Mesa Rim Road, San Diego CA 92121, USA

AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

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

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

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,

TÜV®

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

A1 / 04.11

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

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L. TUV
IDNO 1003602008134
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

Product Service

CERTIFICATE

No. Q1N 16 05 42074 027

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

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

Certification Mark:

tuv-sud.com/ps-cert

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

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

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

Report No.: SH1610619

Valid from: 2016-07-15
Valid until: 2019-07-14

Date, 2016-07-08

Stefan Preiß

0405276800898

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-PL-...

REPUBLICA MOLDOVA, mun. CHIŞINĂU PENTRU CONTRACTE ŞI FACTURI "SANMEDICO" S.R.L. IDNO 1003602006154 SOCIETATE CU RĂSPUNDERE LIMITATĂ

DAkkS CRT2 / 10.13

HIMEDIA®
For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 01st December 2017

STATEMENT

We, **HiMedia Laboratories Pvt. Ltd.**, having a registered office at A-516, Swastik Disha Business Park, Via Vadhani Industrial Estate, L.B.S. Marg, Mumbai – 400 086, INDIA, 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.

For HIMEDIA LABORATORIES PVT. LTD.,

HIMEDIA LABORATORIES PVT. LTD. Himedia

Mr. V.M.WARKE.

DIRECTOR – SALES & MARKETING

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6116 9797 / 2500 1607 | Fax : 00-91-22-2500 2286
CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel : 00-91-22-6147 1919 / 2500 3747 | Fax : 00-91-22-6147 1920 / 2500 5764 | Email : info@himedialabs.com
Web : www.himedialabs.com

ISO 9001:2015 CERTIFIED
ISO 13485:2012 CERTIFIED
"...expect only quality from us"
CIN : U85195MH1982PTC028094

REPUBLICA MOLDOVA, mun. CHIŞINĂU
PENTRU CONTRACTE ŞI FACTURI
"SANMEDICO" S.R.L.
IDNO 1003602006154
TATEA CU RĂSPUNDERE LIMITATĂ

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **HiMedia Laboratories Pvt. Ltd.**

Address: 23 Vadhani Industrial Estate,LBS Marg, Mumbai - 86, MS, India
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) *(groupnames /.)*:

Group	Group name	NL registration no.	No.
DCM&S	Dehydrated Culture Media & Supplements	NL-CA002-2013-26442	1
RPM	Ready Prepared Media Subgroups: Ready Prepared Plates, Ready Prepared Liquid & Solid Medium, Ready Prepared Slants,Ready Prepared Dual Media, HiDip Slides, HiSafe Blood Culturing System, Transport Medium w/ swabs, Viral Transport Medium w/ swabs, L.J.Medium Slants & Kits, Biochemical Kits for Mycobacteria, UTI Diagnostic Kits, Biochemical Identification Kits	NL-CA002-2013-26448	2
ESK	Epidemiological Screening Kit: Subgroups: Hi Aureus Confirmation Kits	NL-CA002-2012-24117	3
ASS	Antimicrobial Susceptibility Systems Subgroups: Sensitivity Discs-Single & Multi Discs MIC Strips: HiComb Strips & Ezy MIC Strips	NL-CA002-2013-26444	4
BDA	Bacteriological Differentiation Aids Subgroups: Readymade Stains, Indicators & Reagents in liquid, Differentiation Discs & Strips, HiDtect Rapid Identification Discs	NL-CA002-2013-26445	5
CCM	Cell Culture Media Subgroups: Karyotyping Media, Stem Cell Differentiation Media & Supplements, Stem Cell Freezing Medium, Stem Cell Differentiation Kits ,Viral Transport Medium, Balanced Salt Solutions, Antibiotic solutions, Animal Cell Culture Medium Liquid	NL-CA002-2013-26446	6
MBP	Molecular Biology Products Subgroups: DNA & RNA Isolation Kits, Latex Agglutination Kits, Haematology Kits, Density gradient Separation Medium, PCR Kits	NL-CA002-2013-26447	7

type and model numbers; 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

Mumbai, India; 2018-30-10

Dr. G.M.Warke , Managing Director

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

(name; function and signature of manufacturer)

Product group	Type/ Model / Ref number	Device Name	Risk Class	Date of CE compliance
Bacteriological Differentiation Aids				
BDA- HiDtect Rapid Identification Discs	DT001	HiDtect™ UTI Identification Disc	Low risk	20/12/2012
BDA- HiDtect Rapid Identification Discs	DT003	HiDtect™ Pseudomonas Identification Disc	Low risk	20/12/2012
BDA- HiDtect Rapid Identification Discs	DT015	HiDtect™ Universal Enviro Identification Disc	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I001	Andrade's Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I002	Bromocresol Green Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I003	Bromocresol Purple Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I004	Bromophenol Blue Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I005	Bromothymol Blue Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I006	Methyl Orange Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I007	Methyl Red Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I008	Neutral Red Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I009	Phenolphthalein, 0.1% w/v	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I010	Phenol Red Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I011	Thymol Blue Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I012	Thymolphthalein Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I013	Universal Indicator	Low risk	20/12/2012
BDA- Readymade Indicators in Liquid	I014	Mixed Indicator Solution (25X)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K001	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K001CCL	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K001D	Gram Staining Kit	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K001L	Gram Stains - Kit (contains S012, S032, S013 and S027 or S038)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K002	Albert's Metachromatic Stains - Kit	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K002L	Albert's Metachromatic Stains - Kit	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K003	Neisser's Metachromatic Stains - Kit (contains S013, S023 and S037)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K003L	Neisser's Metachromatic Stains - Kit (contains S013, S023 and S037)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K004	Capsule Stains - Kit (contains S021, S025 and S047)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K004L	Capsule Stains - Kit (contains S021, S025 and S047)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K005	ZN Acid Fast Stains - Kit (contains S033,S005 and S022)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K005CCL	ZN Acid Fast Stains - Kit (contains S033,S005 and S022)	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K005D	ZN Acid Fast Stains - Kit	Low risk	04/07/2018
BDA- Readymade Stains in Liquid	K005L	ZN Acid Fast Stains - Kit (contains S033, S005 & S022)	Low risk	20/12/2012
BDA- Readymade Stains in Liquid	K006	Schaeffer & Fulton's Spore Stains - Kit (contains S022 and S029)	Low risk	20/12/2012

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23, Vadhani Industrial Estate L.B.S.Marg, Ghatkopar (W), Mumbai - 400086, Maharashtra, India

Unit-1: B-4-5-6, MIDC, Palkhed, Dindori, Nashik - 422 022, Maharashtra, India

Design and Development, Manufacturing and Supply of Biosciences Products for application in Microbiology (including Dehydrated culture Media, Antimicrobial Susceptibility Systems, Culture Media Bases and Bacteriological Diffrentiation Aids), Animal Tissue Culture, Plant Tissue Culture, Molecular Biology

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Registration No.: 17285/0

Date of initial issue: 29 December 2015

Valid until: 21 November 2020

Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH, AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber
General Manager

Dr. Mag. Anni Koubek
Specialist representative

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EN ISO 13485:2012

Medical devices - Quality management systems - Requirements for regulatory purposes

Registration No.: 00275/0

Date of initial issue: 21 November 2017

Valid until: 31 March 2019

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Vienna, 22 November 2017

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH, AT-1010 Vienna, Zelinkagasse 10/3

Konrad Scheiber General Manager	Ing. Andreas Aichinger, MSc Specialist representative

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

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IDNO 1003

CERTIFICATE

Quality Austria Central Asia Private Limited
(A Division of Peacock Global Company)
Awards this Certificate to

HiMedia Laboratories Pvt. Ltd.
Unit I : B/4-6, MIDC, Palkhed, Dindori, Nashik-422 202, Maharashtra, India
Unit II : W-239(B), MIDC Phase II, Shivaji Udyog Nagar, Dombivli, District Thane – 421 204, Maharashtra, India
Unit III : D-61 MIDC, Phase-II, Near Shani Mandir, Dombivli, District Thane – 421204, Maharashtra, India

This Certificate confirms the application and further development of an effective

WHO GMP Compliance System

Complying with the requirement of

WHO GMP Guidelines

Unit I : Manufacture & supply of Biosciences products for applications in Microbiology (includes Dehydrated Culture Media, Culture Media Bases, Antimicrobial Susceptibility Systems & Bacteriological Differentiation Aids), Animal Cell Culture, Plant Tissue Culture and Molecular Biology
Unit II : Manufacture and supply of Sterile Ready Prepared Media
Unit III : Manufacture and supply of Sterile Ready Prepared Media

Report No.:QACA/WHO/069
Issue Date: 21/12/2016
Expiry Date: 20/12/2019

The validity of this Certificate will be maintained via annual surveillance audits and one renewal audit after three years.

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India: 20 Dec 2016
Quality Austria Central Asia Private Limited (A division of Peacock Global company)

Alok Kumar
Country Head

The Product and Systems Liability rests with the manufacturer and under no circumstances Quality Asustria Central Asia Shall be Held Responsible

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