

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:

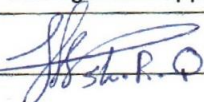
See Attached list

- 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	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

Catalogue 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 (Horse 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	Waalser 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 Coagulation Control
8.02.61	Abnormal Coagulation Control
8.02.44	PT Kit
8.02.45	APTT (PTT) Kit

Catalogue 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: Leucocytes, 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 Diagnostic Products

Catalogue 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 Combostest Cassette, Stool Sample
8.04.74	Rota-Adeno Antigens Combostest 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 Virus Test 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
Catalogue No	Description
8.05.03	Alkaline Phosphatase Kinetic, DGKC Method (Tablets)

Catalogue 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	Methylenedioxyamphetamine (MDMA) Ecstasy Test Cassette, Urine
8.16.05	Methylenedioxyamphetamine (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)

Atlas Medical
Quality Diagnostic Products

[Signature]
S.R.P.

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 Thyocyanate Colorimetric
8.05.11	Cholesterol Liquid (CHOD-POD)
8.05.26	HDL Cholesterol Precipitating Reagent
8.05.51	HDL Cholesterol, 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)

Catalogue 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

Catalogue 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	CEFACTOR (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 / SULBACTAM (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 Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.21	CEFTRIOXONE (30 µg) - FR(5 Cartridge x 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(5Cartridge x50 Discs with Cartridge Applicator per Box)

Catalogue No	Description
8.39.24	CEPHALORIDINE (30 µg)-CH(5Cartridge x50 Discs with Cartridge Applicator per Box)
8.39.25	CEPHALOTHIN (30 µg) -CA(5Cartridge x 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(5Cartridge x 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	LEVOFLOXACIN (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)

Catalogue 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

Catalogue 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)



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



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

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.



Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc. S.A.

jalvarenga@aconlabs.com

+1 858 875 8085



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

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Cerbari Oleg, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

A handwritten signature in black ink, appearing to read "Jassy Alvarenga", is written over a red circular stamp.



Jassy Alvarenga
International Account Manager
ACON Laboratories, Inc
jalvarenga@aconlabs.com
+1 858 875 8085

Certificate

Of Marketing Authorization of Medical Product

Nr. **AR/IVMD/Xema/12-2016**

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

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

Manufacturer:
Hersteller

Xema Co., Ltd.

bld.4, 48, The 9th Parkovaya str.
Moscow 105264, RUSSIA,
info@xema.ru; www.xema.ru

Product name:
Produkt

See annex to the Certificate

Siehe Anhang zum Zertifikat

Product Classification:
Produktklassifizierung

In Vitro Diagnostic Medical Devices

In-vitro-Diagnostikum (IVD) Medizinprodukte

Category:
Kategorie

Common/ Other IVD

Sonstige IVD-Produkte

Conformity Module:
Konformitätsmodul

**Module A (EC Declaration of Conformity)
(Annex III, except 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 Registrationsnummer
(Gemäß Artikel 10 der Richtlinie 98/79 / EG)

See annex to the Certificate

Siehe Anhang zum Zertifikat

Date of issue: 2016-12-31
Das Ausstellungsdatum

Valid to : 2019-12-31
Gültig bis

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



Polmed.de

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

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

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

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

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

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

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

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

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

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

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVMD/Xema/12-2016

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

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

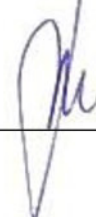
	Nomenclature term Nomenklaturbezeichnung	Catalog number Katalognummer	Name of device Produktbezeichnung	DIMDI Product registration number Registriernummer
50.	NEURON SPECIFIC ENOLASE	K234	NSE EIA Cat. Nr K234	DE/CA37/IVD/13/52
51.	OTHER OTHER TUMOUR MARKERS	K239	HE – 4 EIA Cat. Nr K239	DE/CA37/IVD/13/53
52.	HSV IgG	K104	HSV ½ IgG EIA (Cat. Nr K104)	DE/CA37/IVD/13/67
53.	HSV IgM	K104M	HSV ½ IgM EIA (Cat. Nr K104M)	DE/CA37/IVD/13/66
54.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA (Cat. Nr K106)	DE/CA37/IVD/13/65
55.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	Treponema pallidum Total Ab EIA (Cat. Nr K111)	DE/CA37/IVD/13/64
56.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA (Cat. Nr K111G)	DE/CA37/IVD/13/63
57.	SYPHILIS ANTIBODY IGM	K111M	Treponema pallidum IgM EIA (Cat. Nr K111M)	DE/CA37/IVD/13/62
58.	H. PYLORI ANTIBODY ASSAYS	K119	H.pylori IgG EIA (Cat. Nr K119)	DE/CA37/IVD/13/61
59.	H. PYLORI ANTIBODY ASSAYS	K119M	H.pylori IgM EIA (Cat. Nr K119M)	DE/CA37/IVD/13/60
60.	ASPERGILLUS	K121	Aspergillus IgG EIA (Cat. Nr K121)	DE/CA37/IVD/13/59
61.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA (Cat. Nr K126)	DE/CA37/IVD/13/58
62.	GIARDIA LAMBLIA	K171	Giardia lamblia Total Ab EIA (Cat. Nr 171)	DE/CA37/IVD/13/57
63.	OTHER TUMOUR MARKER RAPID TESTS	X220V	XEMAtestOvaScreen (Cat. Nr X220V)	DE/CA37/IVD/13/56
64.	OTHER TUMOUR MARKER RAPID TESTS	X222	XEMAtestCA125 (Cat. Nr X222)	DE/CA37/IVD/13/55
65.	OTHER TUMOUR MARKER RAPID TESTS	X239	XEMAtestHE4 (Cat. Nr X239)	DE/CA37/IVD/13/54
66.	IMMUNOGLOBULIN A IgA	K276	SECRETORY IgA (sIgA) EIA (Cat. No. K276)	DE/CA37/IVD/13/68
67.	ECHINOCOCCUS	K175	Cestodes IgG EIA (Cat. No. K175)	DE/CA37/IVD/13/72E
68.	DISTOMATOSIS	K176	Fasciola IgG EIA (Cat. No. K176)	DE/CA37/IVD/13/71E
69.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	Free Testosterone EIA (Cat. No. K219)	DE/CA37/IVD/13/70E
70.	HUMAN PLACENTAL LACTOGEN HPL	K246	Human Placental Lactogen EIA (Cat. No. K246)	DE/CA37/IVD/13/69E

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

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



Date: December 31, 2016



Polmed.de



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

Page 1 of 4



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



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,

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

Page 4 of 4