



DECLARATION OF CONFORMITY



Rapid Labs Limited Hereby declare that the products listed below, meet the applicable provisions of The Medical Devices Regulations 2002 of the United Kingdom (Statutory Instrument 2002 No. 618) IVD Directive 98/79/EC

Cat Number	Product group name	Size
Febrile Antigen Suspensions		
F-BAAS/1000	Brucella Abortus Antigen	5/1000 ml
F-BMA5/1000	Brucella Melitensis Antigen	5/1000 ml
F-POX5/1000	Proteus OXK Antigen	5/1000 ml
F-POX25/1000	Proteus OX2 Antigen	5/1000 ml
F-POX195/1000	Proteus OX19 Antigen	5/1000 ml
F-SOAS/1000 & HF-SOAS/1000	Salmonella O Antigen Group A	5/1000 ml
F-SOBS/1000 & HF-SOBS/1000	Salmonella O Antigen Group B	5/1000 ml
F-SOCS/1000 & HF-SOCS/1000	Salmonella O Antigen Group C	5/1000 ml
F-SODS/1000 & HF-SODS/1000	Salmonella O Antigen Group D (Typhi O)	5/1000 ml
F-SHAS/1000 & HF-SHAS/1000	Salmonella H Antigen a	5/1000 ml
F-SHBS/1000 & HF-SHBS/1000	Salmonella H Antigen b	5/1000 ml
F-SHCS/1000 & HF-SHCS/1000	Salmonella H Antigen c	5/1000 ml
F-SHDS/1000 & HF-SHDS/1000	Salmonella H Antigen d (Typhi H)	5/1000 ml
F-FPC1 & F-FPC100 & HF-FPC1	Febrile positive control sera	1 ml
F-FNC1 & F-FNC100 & HF-FNC1	Febrile negative control sera	1 ml
F-KIT85	Febrile antigen kit	8x5 ml
F-KIT85C	Febrile antigen kit plus controls	8x5 ml
Rapid Latex		
RL-ASO100 & RL-ASO50	ASO Latex Test Kit	50-100T
RL-CRP100 & RL-CRP50	CRP Latex Test Kit	50-100T
RL-RA100 & RL-RA50	RA (RF) Latex Test Kit	50-100T
RL-HCG100 & RL-HCG50	Pregnancy Latex (indirect) test kit	50-100T
RL-LE100 & RL-LE50	Systemic Lupus Erythematosus Latex test kit	50-100T
RL-Mono50	Mononucleosis Latex Kit	50-100T
RL-STA50	Staphylococcus Latex Kit	50-100T
RL-RB100T	Rose Bengal Agglutination Kit	100T
Syphilis Screening		
D-VDRL100	VDRL Carbon Antigen reagent	100T
D-RPR100 /250/500	RPR Kit	100-500T
RL-TPHA100/200/500	TPHA Kit (haemagglutination)	100-500T
RL-RPR5ML	RPR Reagent 5ml	5ml
RL-RPRP5ML	Syphilis Positive Control 5ml	5ml
Rapid Test Strips & Devices		
D-TPD20 & D-TP50	TP(syphilis) Test - WB/S/P	20/50
D-HCGD20 & D-HCGD40 & D-HCG50	HCG Test - Urine/S/P	20/40/50
D-LHD20 & D-LH50	Ovulation (LH) Test - Urine	20/50
D-HPD40 & D-HP50	H.Pylori Test - WB/S/P	20/50
D-TBD20	TB Test - WB/S/P	20
D-DGMD20 & D-Dgm50	Dengue IgG/IgM tri-line Test - WB/S/P	20/50
D-MPPD20 & D-MPP50	Malaria Pf Test - WB	20/50
D-MPPVD20 & D-MPPV50	Malaria Pf/Pv tri-line Test - WB	20/50
D-AFPD20 & D-AFP50	AFP Test - WB/S/P	20/50
D-FOBD10 & D-FOBS10	Fecal Occult Blood(FOB) Test - feces	20/50
D-TROPD20	Troponin I Test - WB/S/P	20
D-MCKTMD20	Multi-3(Myoglobin/CK-MB/Troponin I) panel - WB/S/P	20
D-DOA1D20 & D-DOA1550	Amphetamine (AMP) Test - Urine	20/50
D-DOA2D20 & D-DOA2550	Methamphetamine (MET) Test - Urine	20/50
D-DOA3D20 & D-DOA3550	Opiates/Morphine (OPI) Test - Urine	20/50
D-DOA4D20 & D-DOA4550	Barbiturates (BAR) Test - Urine	20/50
D-DOA5D20 & D-DOA5550	Benzodiazepines (BZO) Test - Urine	20/50
D-DOA6D20 & D-DOA6550	Cocaine (COC) Test - Urine	20/50
D-DOA7D20 & D-DOA7550	Methadone (MTD) Test - Urine	20/50
D-DOA8D20 & D-DOA8550	Cannabinoids (THC) Test - Urine	20/50
D-DOA9D20 & D-DOA9550	Ketamine (KAN) Test - Urine	20/50
D-DOA10D20 & D-DOA10550	Tricyclic Antidepressants(TCA) Test Urine	20/50
D-DOA11D20 & D-DOA11550	Buprenorphine (BUP) Test - Urine	20/50
D-DOA12D20 & D-DOA12550	Ecstasy (MDMA) Test - Urine	20/50
D-DOA13D20 & D-DOA13550	Phencyclidine (PCP) Test - Urine	20/50
D-DOA14D20	Amphetamine (AMP) Test - Saliva	20
D-DOA15D20	Benzodiazepines (BZO) Test - Saliva	20
D-DOA16D20	Cannabinoids (THC) Test - Saliva	20
D-DOA17D20	Cocaine (COC) Test - Saliva	20
D-DOA18D20	Methamphetamine (MET) Test - Saliva	20
D-DOA19D20	Opiates/Morphine (OPI) Test - Saliva	20
D-DOA20D20	Ecstasy (MDMA) Test Cassette - Saliva	20
D-LEIGMD20	Leishmania IgG/IgM Rapid Test - WB/S/P	20
D-LEIAB50	Leishmania Ab Rapid Test - S/P	50
D-CHABD20	Chagas Ab Rapid Test - WB/S/P	20
D-MPPVD20	Malaria Pf/Pv Ab Rapid Test -WB	20
D-MPPVGD20	Malaria Pf/Pv Ag Rapid Test -WB	20
D-MPPPD20	Malaria Pf Ag Rapid Test -WB	20
D-FILGMD20	Filaria IgG/IgM -WB/S/P	20
D-DGMD20	Dengue IgG/IgM Test -WB/S/P	20
D-DAGMD20	Duo Dengue Ag-IgG/IgM -WB/S/P	20
D-DAGD20	Dengue Ag Rapid Test -WB/S/P	20
D-CHIKMD20	Chikungunya IgM -WB/S/P	20
D-DGMCD20	Dengue+Chikungunya (IgG/IgM-CHIK IgM)	20
D-LEPGMD20	Leptospira IgG/IgM -WB/S/P	20
D-CHAGS50	Cholera Ag Rapid Test - stool	50
D-HPYABD20	H. pylori Ab Rapid Test -WB/S/P	20
D-HPAGD20	H. pylori Ag Rapid Test - stool	20
D-ROTAGD20	Rotavirus Ag Rapid Test - stool	20
D-ROAAGD20	Rota/Adeno Ag Rapid Test - stool	20
D-TYGM20	Typhoid IgG/IgM -S/P	20
D-TYPGMD20	Typhoid IgG/IgM -WB/S/P	20

Cat Number	Product group name	Size
Antibiotic Disks and Rings		
CM-03-M	Antibiotic Monodisc In vials	100
CM-03-M+10	Antibiotic Monodisc In Vials	100
CM-03-M+100	Antibiotic Monodisc In Vials	100
CM-03-X	Identidiscs In Vials	100
CM-03-X+10	Identidiscs In Vials	100
CM-03-OX	Oxidase Discs	100
CM-03-P100	Polydisc In Tins	100
CM-03-P100+25	Polydisc In Tins	100
CM-03-P100+100	Polydisc In Tins	100
CM-03-PE	Esbl Ring In Sachet 25	25
CM-03-TX	Identidisc For Taxonomy	25
CM-03-TXBIL	Bile Identidisc	25
Lectins		
BG-A1L5 & BG-A1L10	Anti-A1 Lectin	5 - 10ml
BG-A1L1L	Anti-A1 Lectin	1000ml
BG-H2 & BG-H5	Anti H Lectin	2 - 5ml
BG-NL2 & BG-NL5	Anti-N Lectin	2 - 5ml
Dehydrated Culture Media		
CM-AAB190	Aeromonas Agar Base	500gm
CM-AB318	Agar Base	500gm
CM-ATMCO48	Amies Transport Medium(modified)w.charcoal(1%)	500gm
CM-AIA151	Anaerob Isolation Agar	500gm
CM-APT370	APT agar	500gm
CM-ADB299	Azide dextrose broth	500gm
CM-BCM289	Bacillus Cereus Medium	500gm
CM-BPA203	Baird Parker Agar	500gm
CM-BHIA175	BHI Agar	500gm
CM-BHIB106	BHI Broth	500gm
CM-BEAA259	Bile Esculin azide agar	500gm
CM-BSA283	Bismuth Sulphite Agar	500gm
CM-BAB109	Blood Agar Base	500gm
CM-BAB120	Blood Agar Base No.2.	500gm
CM-BGA765	Bordet gengou agar	500gm
CM-BTB053	Brewers Thioglycollate Broth	500gm
CM-BGA182	Brilliant Green Agar	500gm
CM-BGA167	Brilliant Green Agar Modified	500gm
CM-BGBB127	Brilliant Green Bile Broth 2%	500gm
CM-BAB131	Brucella Agar Base	500gm
CM-BPW049	Buffered Peptone Water	500gm
CM-CAB254	Campylobacter agar base	500gm
CM-CBM130	Campylobacter Bloodfree Medium	500gm
CM-CEB072	Campylobacter Enrichment Broth	500gm
CM-CBTM054	Cary Blair transport Medium	500gm
CM-CA148	Cetrimide Agar	500gm
CM-CBLA261	China blue lactose agar	500gm
CM-CLED096	CLED D Medium	500gm
CM-CLED097	CLED SI Medium	500gm
CM-CAB137	Columbia Agar Base	500gm
CM-CMM214	Cooked Meat medium	500gm
CM-CMA159	Corn meal agar	500gm
CM-DCAH173	DCA Agar Hynes	500gm
CM-DCAL162	DCA Agar Leifsons	500gm
CM-DTM198	Dermaphyte Test Medium	500gm
CM-DTA077	Dextrose Tryptone agar	500gm
CM-DSSA708	Diagnostic Semi-Solid Salmonella Agar	500gm
CM-DNAA134	Dnase Agar	500gm
CM-DSTA123	DSTA Agar	500gm
CM-ECB263	EC broth	500gm
CM-ECB250	EC broth modified	500gm
CM-EEB161	EE Broth (Mossel)	500gm
CM-EYA376	Egg Yolk Agar	500gm
CM-EMB110	EMB agar	500gm
CM-EA132	Endo Agar	500gm
CM-FBB189	Fraser Broth Base	500gm
CM-GCAB116	GC Agar Base	500gm
CM-GCB401	Giolitti Cantoni broth	500gm
CM-GPB372	Glucose Phosphate Broth	500gm
CM-HEA207	Hektoen Enteric Agar	500gm
CM-HMB210	Hoyle's Medium Base	500gm
CM-ISA031	Iron Sulphite Agar	500gm
CM-ISA085	Iso-Sensitest agar	500gm
CM-KEA154	Kanamycin-Esculin Agar	500gm
CM-KEB089	Kanamycin-Esculin Broth	500gm
CM-KIA194	Kligler Iron Agar	500gm
CM-LB035	Lactose Broth	500gm
CM-LPB258	Lactose phosphate broth	500gm
CM-LTSB297	Lauryl Tryptose (Sulphate) Broth APHA	500gm
CM-LB139	Leethen Broth	500gm
CM-LM236	Litmus milk	500gm
CM-LEB098	Listeria Enrichment Broth FDA	500gm
CM-LIMB188	Listeria Isolation Med. Base Oxford Form	500gm
CM-LJM351	Löwenstein-Jensen Medium	500gm
CM-LDB267	Lysine decarboxylase broth	500gm
CM-LIA090	Lysine Iron Agar	500gm
CM-MAWS185	MacConkey Agar (base)	500gm
CM-MA2174	MacConkey agar No.2	500gm

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D-CHLAGD20	Chlamydia Ag Sample – swab	20
D-GON550	Gonorrhoea Rapid Test – swab	50
D-INFA550	Influenza A/B Rapid Test – swab	50
D-STEPS50	Strep A Rapid Test – swab	50
D-TBSPD20	TB Test IgG/IgM Rapid Test –S/P	20
D-TROPD20	Troponin I Rapid Test – WB/S/P	20
	Urinalysis Strips	
D-U11100 & D-U1150	Urinalysis Strips 11 Parameter	50-100
D-U10100 & D-U1050	Urinalysis Strips 10 Parameter	50-100
D-U9100 & D-U950	Urinalysis Strips 9 Parameter	50-100
D-U8100 & D-U850	Urinalysis Strips 8 Parameter	50-100
D-U7100 & D-U750	Urinalysis Strips 7 Parameter	50-100
D-U6100 & D-U650	Urinalysis Strips 6 Parameter	50-100
D-U5100 & D-U550	Urinalysis Strips 5 Parameter	50-100
D-U4100 & D-U450	Urinalysis Strips 4 Parameter	50-100
D-U3100 & D-U350	Urinalysis Strips 3 Parameter	50-100
D-U2100 & D-U250	Urinalysis Strips 2 Parameter	50-100
D-U1100 & D-U150	Urinalysis Strips 1 Parameter	50-100
	ELISA Kits	
DA-SYTA96	Syphilis Total Antibody 96T (IgG, IgM, IgA)	96
DA-SYTA192	Syphilis Total Antibody 192T (IgG, IgM, IgA)	192
DA-SYTA480	Syphilis Total Antibody 480T (IgG, IgM, IgA)	480
E-115196	HSV 1 IgG	96
E-117196	HSV 2 IgG	96
E-118196	HSV2 IgM	96
E-119196	HSV 1/2 IgG	96
E-120196	HSV 1/2 IgM	96
E-123196	H. pylori Antigen (Ag)	96
E-124196	H. pylori IgG	96
E-201196	AFP	96
E-202196	CEA	96
E-301196	TSH	96
E-302196	Total T4	96
E-303196	Free T4	96
E-304196	Total T3	96
E-305196	Free T3	96
E-401196	Rapid-hCG	96
E-402196	LH	96
E-403196	FSH	96
E-404196	Prolactin	96
E-121196	HEV	96
E-104196	Syphilis TA	96
E-116196	HSV 1 IgM	96

CM-MA3172	MacConkey Agar No.3	500gm
CM-MA5170	MacConkey Agar Sorbitol	500gm
CM-MAN257	MacConkey Agar w/o Crystal Violet	500gm
CM-MANS158	MacConkey Agar w/o Salt	500gm
CM-MBP094	MacConkey Broth Purple	500gm
CM-MEA164	Malt Extract Agar	500gm
CM-MEB050	Malt Extract Broth	500gm
CM-MSA213	Mannitol Salt Agar	500gm
CM-MSB244	Mannitol Salt Broth	500gm
CM-MRD029	Maximal recovery diluent	500gm
CM-MLS095	Membrane lauryl sulphate broth	500gm
CM-MPCA061	Milk Plate Count Agar	500gm
CM-MIM111	Motility-Indol-Urea Base (MIU)	500gm
CM-MB380	Motility Broth	500gm
CM-MRSA205	MRS Agar	500gm
CM-MRSB177	MRS Broth	500gm
CM-MRVP272	MRVP medium	500gm
CM-MSRV086	MSRV AGAR (ISO 6579)	500gm
CM-MHA135	Mueller Hinton Agar NCCLS	500gm
CM-MKB211	Mueller Kaufmann Broth	500gm
CM-NA073	Nutrient Agar	500gm
CM-NBE036	Nutrient Broth Economy	500gm
CM-NB2037	Nutrient Broth No.2 APHA	500gm
CM-OGYE093	O.G.Y.E. Agar Base	500gm
CM-OFM228	OF medium	500gm
CM-OSA122	Orange Serum Agar	500gm
CM-PW038	Peptone Water	500gm
CM-PAB150	Pefferingens Agar Base	500gm
CM-PAAO32	Phenylalanine Agar	500gm
CM-PRA108	Phenol Red Agar	500gm
CM-PRB058	Phenol Red Broth	500gm
CM-PCAAP064	Plate Count Agar APHA	500gm
CM-PCASP051	Plate Count Agar SP	500gm
CM-PDA117	Potato Dextrose Agar	500gm
CM-PDB117	Potato Dextrose Broth	500gm
CM-PAB561	Purple Agar Base	500gm
CM-PAB160	Pseudomonas Agar Base	500gm
CM-RZAM043	R 2 A Medium	500gm
CM-RVB070	Rapport Vassiliadis Broth	500gm
CM-RCA168	Reinforced Clostridal Medium (agar)	500gm
CM-RBA083	Rose Bengal Agar Base	500gm
CM-SDAC393	Sab Dex. agar Chloramp 0,05 g/l	500gm
CM-SDA197	Sab Dex Agar	500gm
CM-SDAC200	Sab Dex agar Chloramphenicol 0,5 g/l	500gm
CM-SDMA275	Sab dextrose-maltose agar	500gm
CM-SLM157	Sabouraud Liquid Medium USP	500gm
CM-SMA201	Sabouraud Maltose Agar	500gm
CM-SSB244	Salmonella Shigella Broth	500gm
CM-MM140	Schaedler Agar	500gm
CM-SDAB255	SDA Beer Medium	500gm
CM-SBB046	Selenite Broth Base	500gm
CM-SCB047	Selenite-Cystine Broth	500gm
CM-STA121	Sensitivity Test Agar	500gm
CM-SMA375	Semisolid media agar	500gm
CM-SIM081	SIM Medium	500gm
CM-SCA063	Simmons Citrate Agar	500gm
CM-SBA143	Slanetz Bartley Agar	500gm
CM-SSA202	SS Agar	500gm
CM-SSB249	SS Broth	500gm
CM-STM042	Stuart Transport Medium	500gm
CM-TCBS183	TCBS	500gm
CM-T7A181	Tergitol 7 Agar	500gm
CM-TBB153	Tetrathionate Broth Base	500gm
CM-TUFM069	Thioglycolat USP Fluid medium	500gm
CM-THB104	Todd Hewitt Broth	500gm
CM-TW039	Tryptone Water	500gm
CM-TPB078	Tryptose Phosphate Broth	500gm
CM-TSA107	TSA	500gm
CM-TSB080	TSB	500gm
CM-TSCA369	TSC Agar	500gm
CM-TSI204	TSI	500gm
CM-UAB066	Urea Agar Base	500gm
CM-UBB028	Urea Broth Base	500gm
CM-VRBA114	Violet Red Bile Agar (lactose)	500gm
CM-VRBG115	Violet Red Bile Glucose	500gm
CM-VJA196	Vogel&Johnson Agar	500gm
CM-WCA274	Wilkins-Chalgren agar	500gm
CM-WLNA209	WL Nutrient Agar	500gm
CM-WA178	Wort Agar	500gm
CM-XLD179	XLD Agar	500gm
CM-YSA192	Yersinia Selective Agar (CIN)	500gm
CM-YAO60	Yeast Agar	500gm
CM-YEA059	Yeast Extract Agar	500gm



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Classification of the above devices under Directive 98/79/EC: Annex III. Other Validity: This Declaration is made in accordance with Article 9(1) of Directive 98/79/EC and is valid from the date shown below.

Date: 7th November 2014

Signed:

Director
Rapid Labs Limited