

DECLARATION OF CONFORMITY

Prestige Diagnostics UK Ltd
40 Ballymena Business Centre
Galgorm, BT42 1FL, NI, UK

We declare the conformity of products listed below according to the essential requirements of Annex I of the Directive 98/79/EC on In Vitro Diagnostic Devices.

The conformity was established by the manufacturer in a conformity assessment procedure according to Annex III of the Directive 98/79/EC.

Prestige Diagnostics UK Ltd

9 September 2020



Alan Rodgers

Managing Director

Attached: List of products

List of Rapid Tests

RADHCG1	HCG PREGNANCY STRIP
RADHCG2	HCG PREGNANCY DEVICE
RADNGH1	GONORRHOEA DEVICE
RADSYP1	SYPHILIS DEVICE
RADSYP2	SYPHILIS STRIPS
RADTNI1	CARDIAC TROPONIN I DEVICE
RADMB01	CK MB DEVICE
RADMYO1	MYOGLOBIN DEVICE
RADCMT1	CARDIAC TRIPLE DEVICE
RADFAB1	FABP DEVICE
RADCRP1	HSCRIP DEVICE
RADNTP1	NT-PRO BNP DEVICE
RADDIM1	D-DIMER DEVICE
RADFOB1	FOB DEVICE
RADAFP1	AFP DEVICE
RADCEA1	CEA DEVICE
RADHAV1	HAV IGM DEVICE
RADHAV3	HAV IGG/IGM DEVICE
RADHBG1	HBSAG STRIP
RADHBG2	HBSAG DEVICE
RADHBS1	ANTI HBS DEVICE
RADHEG1	HBEAG DEVICE
RADHEB1	HBEAB DEVICE
RADHBC2	HBCAB DEVICE
RADHBV1	HBV COMBO DEVICE
RADHCV1	HCV STRIP
RADHCV2	HCV DEVICE
RADHEV1	HEV IGM DEVICE
RADTB01	TB ANTIBODY DEVICE
RADHPG1	H.PYLORI ANTIGEN DEVICE
RADHPB1	H.PYLORI ANTIBODY DEVICE
RADMAL1	MALARIA PAN DEVICE
RADMAL2	MALARIA PF DEVICE
RADSTA1	STREP A DEVICE
RADSTB1	STREP B DEVICE
RADDEN1	DENGUE DUAL AG AB
RADDEN2	DENGUE ANTIBODY DEVICE
RADRDN1	ROTADENO COMBO DEVICE
RADMAU1	MICROALBUMIN DEVICE
RADMPN1	MYCOPLASMA DEVICE
RADTYP1	SALMONELLA (TYPHOID) DEVICE
RADALC1	SALIVARY ALCOHOL STRIP
RADMTD1	MULTIDRUG (10 drugs) DEVICE
RADMTD2	MULTIDRUG (6 drugs) DEVICE
RADMTD3	AMPHETAMINE DEVICE
RADMTD4	BARBITURATES DEVICE

RADMTD5	BUPRENORPHINE DEVICE
RADMTD6	BENZODIAZEPAM DEVICE
RADMTD7	COCAINE DEVICE
RADMTD8	COTININE DEVICE
RADMTD9	EDDP DEVICE
RADMTD10	KETAMINE DEVICE
RADMTD11	MDMA DEVICE
RADMTD12	METHAMPHETAMINE DEVICE
RADMTD13	METHADONE DEVICE
RADMTD14	MORPHINE DEVICE
RADMTD15	PCP DEVICE
RADMTD16	TCA DEVICE
RADMTD17	THC DEVICE
RADCOV1	2019-nCOV IGG IGM DEVICE
RADCOV2	2019-nCOV IGG IGM WB DEVICE
RADCOV4	2019-nCoV ANTIGEN DEVICE
RADCOV5	2019-nCoV AND INF A+B ANTIGEN DEVICE