



DECLARATION OF CONFORMITY

for the Fluorescence Immunoassay

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Rapid Strips & devices
Legal Manufacturer: (Name on Label)	Rapid Labs Limited Unit 2 & 2A Hall Farm, Business Centre, Church road, Little Bentley, Colchester, Essex, CO7 8SD United Kingdom
SRN:	GB-MF-000026335
Basic UDI-DI:	N/A
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Professional use
IVDR Classification:	As per Appendix II (This document) – Product Listing/Schedule
Notified Body:	N/A
CE Certificate:	N/A
EU Authorised Representative:	VidaQuick Biotech S.L. No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain
EU Authorised Representative SRN:	N/A
IVDR Assessment Route:	<i>Provide indication of conformity assessment route chosen in accordance with Article 48 of the IVDR. For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746. If Class A provided sterile, must also apply the procedures laid out in Annex IX or Annex XI.</i>

Name Judy Zhang

Position Quality Manager

Signed

Date 22/05/2022

Place Colchester, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

Appendix II –Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code	Class	Rule
D-FICEAD20	CEA Test Device -S/P	54616	B	6
D-FIAFPD20	AFP Test Device -S/P	54060	B	6
D-FIDIMERD10	D-Dimer Test Device -WB/P	61389	C	3k
D-FICKMBD10	CK-MB Test Device -WB/S/P	61385	C	3j
D-FIMYOD25	Myoglobin Rapid Test Device —WB/S/P	61390	B	6
D-FIFABD10	H-FABP Test Device -WB/S/P	53365	C	3j
D-FINTPD10	NT-proBNP Test Device -WB/S/P	47352	C	3j
D-FITIMCKD20	Troponin I/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FITTMCKD20	Troponin T/Myoglobin/CK-MB (3 in 1) Test Device -WB/S/P	47384	C	3j
D-FILHD20	LH Test Device -WB/S/P	65959	B	6
D-FISTRAS20	Strep A Test Device -Swab	63770	B	6
D-FIIABD20	Influenza A+B Test Device -Swab	49117	B	6
D-FIDGMD20	Dengue IgG/IgM Test Device -WB/S/P	48915	C	3b
D-FIDAGD25	Dengue NS1 Test Device -WB/S/P	48915	C	3b
D-FIRSVD20	RSV Test Device -Swab	62587	B	6
D-FISPD10	Streptococcus pneumoniae Test Device -urine	63796	B	6
D-FILPD25	Legionella pneumophila Test Device -urine	63781	B	6
D-FITSPD40	Syphilis Test Device -WB/S/P	51814	C	3a
D-FIAMHD10	AMH Test Device -WB/S/P	58410	B	6
D-FIFSHD20	FSH Test Device -WB/S/P	54188	B	6
D-FIRFSPD20	Rheumatoid Factor Rapid Test device-S / P	55109	B	6
D-FICRPD25	CRP Test Device-WB/S/P	58768	B	6
D-FIPCTD25	PCT Test Device-WB/S/P	54313	B	6
D-FIFOBD25	FOB Test Device-Feces	66044	B	6
D-FIHCGD25	β-HCG Test Device-S/P	58789	B	6
D-FITSHD25	TSH Test Device-S/P	54384	B	6
D-FITESD25	Testosterone Test Device-S/P	54184	B	6
D-FIP4D25	Progesterone(P4) Test Device-S/P	54327	B	6
D-FICYSCD25	CysC Test Device-WB/S/P	48177	C	3j
D-FI2MGD25	β2MG Test Device-WB/S/P	53930	B	6
D-FINGALD25	N-GAL Test Device-Urine	47426	B	6
D-FIHBA1CD25	HbA1c Test Device-WB	65958	B	6
D-FIIGED25	IgE Test Device-WB/S/P	60380	B	6
D-FIFED25	Ferritin Rapid test Device -WB/S/P	58769	B	6
D-FICOVID10	COVID-19 Antigen Rapid Test Device-Nasopharyngeal Swab	64787	B	6
D-FIPRLD10	PRL (Prolactin)Test device-WB/S/P	58765	B	6
D-FIPRLD25	PRL (Prolactin)Test device-WB/S/P	58765	B	6
D-FIT3WBD10	T3 Test Device-WB/S/P	63082	B	6

D-FIT3WBD25	T3 Test Device-WB/S/P	63082	B	6
D-FIVDWBD25	Vitamin D Rapid Test Device-WB/S/P	65347	B	6
D-FIVDWBD10	Vitamin D Rapid Test Device-WB/S/P	65347	B	6
D-FITROPD25	cTnI Test Device-WB/S/P	54010	C	3j
D-FITROPD10	cTnI Test Device-WB/S/P	54010	C	3j
D-FIPNEUD20	Mycoplasma pneumoniae Antigen Test Device - Throat Swab	51213	B	6
D-FIHCGWBD25	β -HCG Test Device-WB/S/P	63072	B	6
D-FIPSAD10	PSA Test Device -S/P	54670	C	3h
D-FIPSAWBD10	PSA Test Device-WB/S/P	54670	C	3h
D-FIPSAWBD25	PSA Test Device-WB/S/P	54670	C	3h
D-FIT4WBD10	T4 Test Device-WB/S/P	63072	B	6
D-FIT4WBD25	T4 Test Device-WB/S/P	63072	B	6
D-FITSHWBD10	TSH Test Device-WB/S/P	54384	B	6
D-FITSHWBD25	TSH Test Device-WB/S/P	54384	B	6
D-FIFT3WBD10	FT3 Test Device -WB/S/P	54419	B	6
D-FIFT3WBD25	FT3 Test Device -WB/S/P	54419	B	6
D-FIFT4WBD10	FT4 Test Device -WB/S/P	63071	B	6
D-FIFT4WBD25	FT4 Test Device -WB/S/P	63071	B	6
D-FIIGAWBD10	IgA Test Device -WB/S/P	0	B	6
D-FIIGAWBD25	IgA Test Device -WB/S/P	0	B	6
D-FIhsCTIK10	High-Sensitivity Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FIhsCTIK25	High-Sensitivity Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FICTNTD10	Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FICTNTD25	Cardiac Troponin T Test Device-WB/S/P	54004	C	3j
D-FIMALD10	Malaria P.f./P.v./Pan Test Device--WB/S/P	52364	B	6
D-FIMALD25	Malaria P.f./P.v./Pan Test Device--WB/S/P	52364	B	6
D-FIHPD10	H. pylori Antigen Test Device-Feces	65668	B	6
D-FIHPD25	H. pylori Antigen Test Device-Feces	65668	B	6
D-FICALD10	Calprotectin Test Device-Feces	53627	B	6
D-FICALD25	Calprotectin Test Device-Feces	53627	B	6
D-FIROTD10	Rotavirus Test Device-Feces	50245	B	6
D-FIROTD25	Rotavirus Test Device-Feces	50245	B	6
D-FIADFD10	Adenovirus Antigen Test Device-Feces	49854	B	6
D-FIADFD25	Adenovirus Antigen Test Device-Feces	49854	B	6
D-FIADNSD10	Adenovirus pneumoniae Antigen Test Device-Nasopharyngeal Swab	49854	B	6
D-FIADNSD25	Adenovirus pneumoniae Antigen Test Device-Nasopharyngeal Swab	49854	B	6
D-FIAFPWBD10	AFP Test Device -WB/S/P	54060	C	3h
D-FIAFPWBD25	AFP Test Device -WB/S/P	54060	C	3h
D-FIAMITFWBD10	Troponin T/Myoglobin/CK-MB (3in1) Test Device-	47384	C	3j

	Fingerstick WB, WB/S/P			
D-FIAMITFWBD25	Troponin T/Myoglobin/CK-MB (3in1) Test Device-Fingerstick WB, WB/S/P	47384	C	3j
D-FIARNSD10	Adenovirus pneumoniae and RSV Combo Test Device-Nasopharyngeal Swab	48243	B	6
D-FIARNSD25	Adenovirus pneumoniae and RSV Combo Test Device-Nasopharyngeal Swab	48243	B	6
D-FIASOFWBD10	Anti-streptolysin O (ASO) Test Device-Fingerstick-WB, WB/S/P	63271	B	6
D-FIASOFWBD25	Anti-streptolysin O (ASO) Test Device-Fingerstick-WB, WB/S/P	63271	B	6
D-FIBMGFWBD10	β 2MG Test Device-Fingerstick WB, WB/S/P	53930	B	6
D-FIBMGFWBD25	β 2MG Test Device-Fingerstick WB, WB/S/P	53930	B	6
D-FICEAWBD10	CEA Test Device -WB/S/P	54616	C	3h
D-FICEAWBD25	CEA Test Device -WB/S/P	54616	C	3h
D-FICSGFWBD10	COVID-19 S-RBD IgG Antibody Test Device-Fingerstick-WB, WB/S/P	64836	B	6
D-FICSGFWBD25	COVID-20 S-RBD IgG Antibody Test Device-Fingerstick-WB, WB/S/P	64836	B	6
D-FICTNTFWBD10	cTnT Test Device-Fingerstick-WB, WB/S/P	54004	C	3j
D-FICTNTFWBD25	cTnT Test Device-Fingerstick-WB, WB/S/P	54004	C	3j
D-FIDOAAAMPD10	Single Drug Amphetamine (AMP) Test Device - Urine	55459	B	6
D-FIDOAAAMPD25	Single Drug Amphetamine (AMP) Test Device - Urine	55459	B	6
D-FIDOAAPVPD10	Single Drug α -Pyrrolidinovalerophenone (α -PVP) TestDevice - Urine	55459	B	6
D-FIDOAAPVPD25	Single Drug α -Pyrrolidinovalerophenone (α -PVP) TestDevice - Urine	55459	B	6
D-FIDOABARD10	Single Drug Barbiturates (BAR) Test Device - Urine	55459	B	6
D-FIDOABARD25	Single Drug Barbiturates (BAR) Test Device - Urine	55459	B	6
D-FIDOABZOD10	Single Drug Benzodiazepines (BZO) Test Device - Urine	55459	B	6
D-FIDOABZOD25	Single Drug Benzodiazepines (BZO) Test Device - Urine	55459	B	6
D-FIDOAC OCD10	Single Drug Cocaine (COC) Test Device - Urine	55459	B	6
D-FIDOAC OCD25	Single Drug Cocaine (COC) Test Device - Urine	55459	B	6
D-FIDOAKETHD10	Single Drug Ketamine (KET) Test Device - Hair	55459	B	6
D-FIDOAKETHD25	Single Drug Ketamine (KET) Test Device - Hair	55459	B	6
D-FIDOAMDMAD10	Single Drug Methylenedioxy-methamphetamine (MDMA) Test Device - Urine	55459	B	6
D-FIDOAMDMAD25	Single Drug Methylenedioxy-methamphetamine (MDMA) Test Device - Urine	55459	B	6
D-FIDOAMETD10	Single Drug Methamphetamine (MET) Test Device - Urine	55459	B	6
D-FIDOAMETD25	Single Drug Methamphetamine (MET) Test Device - Urine	55459	B	6
D-FIDOAMETHD10	Single Drug Methamphetamine (MET) Test Device	55459	B	6

	- Hair			
D-FIDOAMETHD25	Single Drug Methamphetamine (MET) Test Device - Hair	55459	B	6
D-FIDOAMOPD10	Single Drug Morphine (MOP) Test Device - Urine	55459	B	6
D-FIDOAMOPD25	Single Drug Morphine (MOP) Test Device - Urine	55459	B	6
D-FIDOAMOPHD10	Single Drug Morphine (MOP) Test Device - Hair	55459	B	6
D-FIDOAMOPHD25	Single Drug Morphine (MOP) Test Device - Hair	55459	B	6
D-FIDOAMTDD10	Single Drug Methadone (MTD) Test Device - Urine	55459	B	6
D-FIDOAMTDD25	Single Drug Methadone (MTD) Test Device - Urine	55459	B	6
D-FIDOAOPID10	Single Drug Opiate (OPI) Test Device - Urine	55459	B	6
D-FIDOAOPID25	Single Drug Opiate (OPI) Test Device - Urine	55459	B	6
D-FIDOATHCD10	Single Drug Marijuana (THC) Test Device - Urine	55459	B	6
D-FIDOATHCD25	Single Drug Marijuana (THC) Test Device - Urine	55459	B	6
D-FIFERFWBD10	Ferritin Test Device-Fingerstick-WB, WB/S/P	58769	B	6
D-FIFERFWBD25	Ferritin Test Device-Fingerstick-WB, WB/S/P	58769	B	6
D-FIIL6FWBD10	IL-6 Test Device-Fingerstick-WB, WB/S/P	53862	B	6
D-FIIL6FWBD25	IL-6 Test Device-Fingerstick-WB, WB/S/P	53862	B	6
D-FIMDOAHD10	Multi-drug Test Device -Hair	55459	B	6
D-FIMDOAHD25	Multi-drug Test Device -Hair	55459	B	6
D-FISAAFWBD10	SAA Test Device-Fingerstick-WB, WB/S/P	53457	B	6
D-FISAAFWBD25	SAA Test Device-Fingerstick-WB, WB/S/P	53457	B	6
D-FIhsCTID10	High-Sensitivity Cardiac Troponin I Test Device-WB/S/P	54010	C	3j
D-FIhsCTID25	High-Sensitivity Cardiac Troponin I Test Device-WB/S/P	54010	C	3j

Version History

Version	Compiled by	Date	Description
1.0	Judy Zhang	22/10/2024	Initial Issue