



EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT Annex II and NOT self-test)

Manufacturer Guangdong Wesail Biotech Co., Ltd.
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European Representative Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product/s Attached as appendix

Classification Others/General

Conformity Assessment Route Annex III, except point 6, of Directive (Module A)

Applicable Standards

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Signed this Day/ 25th of Month/ February of Year/ 2022, Place (Dongguan), China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp:



Appendix to the DoC

List of medical devices covered by the DoC:

Product Name	Model	Basic UDI-DI	UDI-DI	Intended Use	GMDN Code	EMDN Code
High Sensitivity Cardiac Troponin I Test Kit (Immunofluorescence)	REF No.: BA0010 (20 tests/kit)	697384100A00103K	6973841000857	This kit applies to the quantitative determination of cardiac troponin I (cTnI) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of acute myocardial infarction in clinic.	54010	W0102160703
N-terminal pro-Brain Natriuretic Peptide Test Kit (Immunofluorescence)	REF No.: BA0020 (20 tests/kit)	697384100A00203N	6973841000840	This kit applies to the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of heart failure.	47352	W0102160704
Heart Type Fatty Acid Binding Protein Test Kit (Immunofluorescence)	REF No.: BA0200 (20 tests/kit)	697384100A02003S	6973841000987	This kit applies to the quantitative determination of heart-type fatty acid binding protein (H-FABP) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of acute myocardial infarction clinically.	66449	W0102160705
Myoglobin Test Kit (Immunofluorescence)	REF No.: BA0120 (20 tests/kit)	697384100A01203T	6973841000963	This kit applies to the quantitative determination of myoglobin in human	61390	W0102160702

				serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of myocardial infarction clinically.		
D-Dimer Test Kit (Immunofluorescence)	REF No.: BA0140 (20 tests/kit)	697384100A01403Z	6973841000833	This kit applies to the quantitative determination of D-Dimer in human plasma and whole blood in vitro, and the results cannot be used for the auxiliary diagnosis and exclusion diagnosis of venous thrombosis.	61389	W0103020503
Soluble Growth Stimulation Expressed Gene 2 Protein Test Kit (Immunofluorescence)	REF No.: BA0180 (20 tests/kit)	697384100A01804D	6973841001045	This kit applies to the quantitative determination of soluble growth stimulation expressed gene 2 protein (ST2) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary evaluation of heart diseases clinically.	66308	W01021314
cTnI/CK-MB/Myo Test Kit (Immunofluorescence)	REF No.: BA0130 (20 tests/kit)	697384100A01303W	6973841001007	This kit applies to the simultaneous quantitative determination of cTnI, CK-MB and Myoglobin in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of myocardial infarction clinically.	47384	W01021399
Myeloperoxidase Test Kit (Immunofluorescence)	REF No.: BA0250 (20 tests/kit)	697384100A025049	6973841000970	This kit applies to the quantitative determination of Myeloperoxidase (MPO) in EDTA human plasma and whole blood in vitro.	53131	W01021310
Procalcitonin Test Kit	REF No.: BA0030	697384100A00303R	6973841000864	This kit applies to the quantitative	54313	W0102069013

(Immunofluorescence)	(20 tests/kit)			determination of procalcitonin (PCT) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of bacterial infectious diseases.		
Creatine Kinase Isoenzyme-MB Test Kit (Immunofluorescence)	REF No.: BA0110 (20 tests/kit)	697384100A01103Q	6973841000932	This kit applies to the quantitative determination of creatine kinase MB (CK-MB) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary diagnosis of myocardial infarction, myopathy and other diseases in clinic.	61385	W0102160701
C-Reactive Protein Test Kit (Immunofluorescence)	REF No.: BA0150 (20 tests/kit)	697384100A015044	6973841000871	This kit applies to the quantitative determination of C-reactive protein (CRP) in human serum, plasma and whole blood in vitro. CRP is mainly used as a nonspecific inflammatory biomarker.	58768	W0102160601
Human Serum Amyloid A Test Kit (Immunofluorescence)	REF No.: BA0160 (20 tests/kit)	697384100A016047	6973841001052	This kit applies to the quantitative determination of Serum Amyloid A in human serum, plasma and whole blood in vitro, and is mainly used as a non-specific inflammatory marker.	65297	W01021199
Interleukin-6 Test Kit (Immunofluorescence)	REF No.: BA0170 (20 tests/kit)	697384100A01704A	6973841001069	This kit applies to the quantitative determination of interleukin-6 (IL-6) in human serum, plasma and whole blood in vitro, and is mainly used for monitoring immune status, inflammatory reaction and so on.	66455	W01030609

Glycated Hemoglobin A1c Test Kit (Immunofluorescence)	REF No.: BA0040 (20 tests/kit)	697384100A00403U	6973841000888	This kit applies to the quantitative determination of glycated hemoglobin (HbA1c) in human whole blood in vitro, and is mainly used for auxiliary diagnosis of diabetes and monitoring of blood glucose level in clinic.	53316	W0102160102
Pepsinogen I Test Kit (Immunofluorescence)	REF No.: BA0100 (20 tests/kit)	697384100A01003M	6973841001106	This kit applies to the quantitative determination of pepsinogen (PG I) in human serum, plasma and whole blood in vitro, and clinically, is mainly used for the evaluation of mucinous gland lesions of gastric fundus in clinic.	54290	W0102069006
Pepsinogen II Test Kit (Immunofluorescence)	REF No.: BA0230 (20 tests/kit)	697384100A023043	6973841001120	This kit applies to the quantitative determination of Pepsinogen II in human serum, plasma and whole blood in vitro, and is mainly used for evaluating lesions of the gastric fundic glands clinically.	54294	W0102069006
C Peptide Test Kit (Immunofluorescence)	REF No.: BA0260 (20 tests/kit)	697384100A02604C	6973841001151	This kit applies to the quantitative determination of C Peptide in human serum, plasma and whole blood in vitro, and is mainly used to evaluate function of pancreatic islet in clinic.	65324	W0102060101
Insulin Test Kit (Immunofluorescence)	REF No.: BA0320 (20 tests/kit)	697384100A032045	6973841001113	This kit applies to the quantitative determination of Insulin in human serum, plasma and whole blood in vitro, and is mainly used to evaluate pancreatic function	66119	W0102060103

				in clinic.		
β -human Chorionic Gonadotropin Test Kit (Immunofluorescence)	REF No.: BA0090 (20 tests/kit)	697384100A00904B	6973841000901	This kit applies to the quantitative determination of β -human chorionic gonadotropin (β -hCG) in human serum, plasma and whole blood in vitro, and clinically, is mainly used for the auxiliary diagnosis of ectopic pregnancy and early pregnancy.	66847	W0102050206
Luteinizing Hormone Test Kit (Immunofluorescence)	REF No.: BA0300 (20 tests/kit)	697384100A03003X	6973841001137	This kit applies to the quantitative determination of luteinizing hormone in human serum, plasma and whole blood in vitro.	54255	W0102160304
Anti-Mullerian Hormone Test Kit (Immunofluorescence)	REF No.: BA0190 (20 tests/kit)	697384100A01904G	6973841000925	This kit applies to the quantitative determination of anti-mullerian hormone (AMH) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary assessment of the ovarian reserve.	65295	W0102050215
Follicle Stimulating Hormone Test Kit (Immunofluorescence)	REF No.: BA0380 (20 tests/kit)	697384100A03804P	6973841001144	This kit applies to the quantitative determination of follicle stimulating hormone in human serum, plasma and whole blood in vitro.	65840	W0102160301
Microalbuminuria Test Kit (Immunofluorescence)	REF No.: BA0050 (20 tests/kit)	697384100A00503X	6973841001038	This kit applies to the quantitative determination of microalbuminuria in human urine in vitro, and is mainly used for the auxiliary diagnosis of kidney disease clinically.	63728	W0102010309

Thyroid Stimulating Hormone Test Kit (Immunofluorescence)	REF No.: BA0060 (20 tests/kit)	697384100A006042	6973841000918	This kit applies to the quantitative determination of thyroid stimulating hormone (TSH) in human serum, plasma and whole blood in vitro, and is mainly used for auxiliary evaluation of pituitary thyroid function.	54384	W01020410
Osteocalcin Test Kit (Immunofluorescence)	REF No.: BA0070 (20 tests/kit)	697384100A007045	6973841001243	This kit applies to the quantitative determination of Osteocalcin in human serum, plasma and whole blood in vitro, and clinically, is mainly used for the evaluation of osteoporosis and early osteosynthesis after bone injury.	58758	W0102060311
Ferritin Test Kit (Immunofluorescence)	REF No.: BA0080 (20 tests/kit)	697384100A008048	6973841001236	This kit applies to the quantitative determination of ferritin in human serum, plasma and whole blood in vitro. Clinically, it is mainly used for the auxiliary diagnosis of iron metabolism-related diseases, such as hemochromatosis and iron-deficiency anemia.	58769	W0102070102
Central Nerve Specific Protein 100 β Test Kit (Immunofluorescence)	REF No.: BA0310 (20 tests/kit)	697384100A031042	6973841001014	This kit applies to the quantitative determination of Central Nerve Specific Protein 100 β in human serum, plasma and whole blood in vitro..	57571	W0102039012
Lp-PLA2 Test Kit (FIA)	REF No.: BA0280 (20 tests/kit)	697384100A02804J	6973841000994	This kit applies to the quantitative determination of Lp-PLA2 in human serum, plasma and whole blood in vitro.	67187	W01021312

25-OH VD Test Kit (FIA)	REF No.: BA0290 (20 tests/kit)	697384100A02904M	6973841001021	This kit applies to the quantitative determination of 25-OH VD in human serum, plasma and whole blood in vitro, and clinically, is mainly used for the auxiliary diagnosis of diseases related to vitamin D deficiency.	60955	W0102060309
T3 Test Kit (FIA)	REF No.: BA0224 (20 tests/kit)	697384100A02203Y	6973841001373	This kit applies to the quantitative determination of triiodothyronine (T3) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary evaluation of thyroid function in clinic.	63082	W01020405
T4 Test Kit (FIA)	REF No.: BA0210 (20 tests/kit)	697384100A02103V	6973841000956	This kit applies to the quantitative determination of thyroxine (T4) in human serum, plasma and whole blood in vitro, and is mainly used for the auxiliary evaluation of thyroid function in clinic.	63072	W01020407
AFP Test Kit (FIA)	REF No.: BA0460 (20 tests/kit)	697384100A04604N	6973841001182	This kit applies to the quantitative determination of alpha-fetoprotein (AFP) in human serum, plasma and whole blood in vitro, and is mainly used to monitor the treatment of primary liver cancer.	54060	W0102039001
CEA Test Kit (FIA)	REF No.: BA0440 (20 tests/kit)	697384100A04404G	6973841001175	This kit applies to the quantitative determination of carcinoembryonic antigen (CEA) in human serum, plasma and whole blood in vitro. Clinically, it is used for observing the therapeutic efficacy, predicting	54616	W0102030112

				prognosis, and monitoring recurrence of malignant tumors.		
BNP Test Kit (FIA)	REF No.: BA0480 (20 tests/kit)	697384100A04804U	6973841001168	This kit applies to the quantitative determination of B-type natriuretic peptide (BNP) in human plasma and whole blood in vitro and is mainly used for the auxiliary diagnosis of heart failure in clinic.	47352	W0102160704
PSA Test Kit (FIA)	REF No.: BA0450 (20 tests/kit)	697384100A04504K	6973841000895	This kit applies to the quantitative determination of prostate-specific antigen (PSA) in human serum, plasma and whole blood in vitro, and is mainly used for dynamic monitoring of patients with malignant tumors, and to auxiliary assessment disease progression or treatment effectiveness. It cannot be used as the basis for early diagnosis or diagnosis of malignant tumors, and it cannot be used for tumor screening in the general population.	54666	W0102160202