



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices.

Manufacturer: Lansion Biotechnology Co.,Ltd.

Address: No.6, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, P.R. China

Authorized representative: Lotus NL B.V.

E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive: Reference to Attachment I

Risk Class: Others

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards: Reference to Attachment II

We, the manufacturer, here 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.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Name of authorized signatory: Bingbing Zhao

Position held in the company:

Manager of Quality Department

Date: Dec. 13th, 2023

Seal/Stamp:

Lansion Biotechnology Co.,Ltd.

Place: Nanjing, China

Attachment I

In Vitro Diagnostic Directive:

No.	Product Name
1	25-OH-VD Test Kit (Dry Fluorescence Immunoassay)
2	25-OH-VD3 Test Kit(Dry Fluorescence Immunoassay)
3	ACT Coagulation Analyzer Test Strip(Electrochemistry)
4	AD7c-NTP Test Kit(Dry Fluorescence Immunoassay)
5	AI Test Kit (Dry Fluorescence Immunoassay)
6	AII Test Kit (Dry Fluorescence Immunoassay)
7	ALD Test Kit (Dry Fluorescence Immunoassay)
8	AMH Test Kit(Dry Fluorescence Immunoassay)
9	APTT Coagulation Analyzer Test Strip(Electrochemistry)
10	ASFV-Ab Test Kit(Dry Fluorescence Immunoassay)
11	ASO Test Kit(Dry Fluorescence Immunoassay)
12	A β 1-42 Test Kit(Dry Fluorescence Immunoassay)
13	B12 Test Kit (Dry Fluorescence Immunoassay)
14	BNP Test Kit(Dry Fluorescence Immunoassay)
15	CCP Test Kit(Dry Fluorescence Immunoassay)
16	CK-MB Test Kit(Dry Fluorescence Immunoassay)
17	cMyBP-C Test Kit(Dry Fluorescence Immunoassay)
18	Crea Test Kit(Dry Fluorescence Immunoassay)
19	CRP Test Kit(Dry Fluorescence Immunoassay)
20	CRP/RF/ASO Test Kit(Dry Fluorescence Immunoassay)
21	cTnI /CK-MB/Myo Test Kit(Dry Fluorescence Immunoassay)
22	cTnI Test Kit(Dry Fluorescence Immunoassay)
23	cTnI/NT-proBNP/D-Dimer Test Kit(Dry Fluorescence Immunoassay)
24	cTnT Test Kit(Dry Fluorescence Immunoassay)
25	Cys-C Test Kit(Dry Fluorescence Immunoassay)
26	D-Dimer Coagulation Analyzer Test Strip(Electrochemistry)

27	D-Dimer Test Kit(Dry Fluorescence Immunoassay)
28	E2 Test Kit(Dry Fluorescence Immunoassay)
29	FDP Test Kit(Dry Fluorescence Immunoassay)
30	Ferritin Test Kit(Dry Fluorescence Immunoassay)
31	FIB Coagulation Analyzer Test Strip(Electrochemistry)
32	FluA IgM Test Kit(Dry Fluorescence Immunoassay)
33	FluB IgM Test Kit(Dry Fluorescence Immunoassay)
34	Folic Acid Test Kit (Dry Fluorescence Immunoassay)
35	FSH Test Kit(Dry Fluorescence Immunoassay)
36	FT3 Test Kit(Dry Fluorescence Immunoassay)
37	FT4 Test Kit(Dry Fluorescence Immunoassay)
38	G-17 Test Kit(Dry Fluorescence Immunoassay)
39	Hair Drug Test Kit for KET(Dry Fluorescence Immunoassay)
40	Hair Drug Test Kit for MET(Dry Fluorescence Immunoassay)
41	Hair Drug Test Kit for MOP(Dry Fluorescence Immunoassay)
42	HbA1c Test Kit(Dry Fluorescence Immunoassay)
43	HCY Test Kit(Dry Fluorescence Immunoassay)
44	H-FABP Test Kit(Dry Fluorescence Immunoassay)
45	hs-cTnl Test Kit(Dry Fluorescence Immunoassay)
46	IgG4 Test Kit(Dry Fluorescence Immunoassay)
47	IL-6 Test Kit(Dry Fluorescence Immunoassay)
48	Influenza A Test Kit(PCR Fluorescence Probing)
49	Influenza B Test Kit(PCR Fluorescence Probing)
50	INHB Test Kit (Dry Fluorescence Immunoassay)
51	LH Test Kit(Dry Fluorescence Immunoassay)
52	Lp-PLA2 Test Kit(Dry Fluorescence Immunoassay)
53	mAlb Test Kit(Dry Fluorescence Immunoassay)
54	MPO Test Kit(Dry Fluorescence Immunoassay)

55	Myo Test Kit(Dry Fluorescence Immunoassay)
56	NGAL Test Kit(Dry Fluorescence Immunoassay)
57	NT-proBNP Test Kit(Dry Fluorescence Immunoassay)
58	PCT Test Kit (Dry Fluorescence Immunoassay)
59	PCT Test Kit(Dry Fluorescence Immunoassay)
60	PCT/CRP Test Kit(Dry Fluorescence Immunoassay)
61	PCT/IL-6 Test Kit(Dry Fluorescence Immunoassay)
62	PGI/PGII Test Kit(Dry Fluorescence Immunoassay)
63	PRL Test Kit(Dry Fluorescence Immunoassay)
64	Progesterone Test Kit(Dry Fluorescence Immunoassay)
65	PSA Test Kit(Dry Fluorescence Immunoassay)
66	PT Coagulation Analyzer Test Strip(Electrochemistry)
67	PT/ACT Coagulation Analyzer Test Strip (Electrochemistry)
68	PT/APTT Coagulation Analyzer Test Strip (Electrochemistry)
69	PT/APTT/ACT Coagulation Analyzer Test Strip (Electrochemistry)
70	PT/APTT/FIB/TT Coagulation Analyzer Test Strip(Electrochemistry)
71	PT/APTT/FIB/TT/ACT Coagulation Analyzer Test Strip(Electrochemistry)
72	PT/APTT/TT Coagulation Analyzer Test Strip (Electrochemistry)
73	PT/TT Coagulation Analyzer Test Strip (Electrochemistry)
74	P-tau-181 Test Kit(Dry Fluorescence Immunoassay)
75	Renin Test Kit (Dry Fluorescence Immunoassay)
76	RF Test Kit(Dry Fluorescence Immunoassay)
77	RNA Diagnostic Kit(PCR Fluorescence Probing)
78	S100- β Test Kit(Dry Fluorescence Immunoassay)
79	SAA Test Kit(Dry Fluorescence Immunoassay)
80	SAA/CRP Test Kit(Dry Fluorescence Immunoassay)
81	SARS-CoV-2 Neutralizing Antibodies(Dry Fluorescence Immunoassay)
82	ST2 Test Kit(Dry Fluorescence Immunoassay)

83	Testosterone Test Kit(Dry Fluorescence Immunoassay)
84	TSH Test Kit(Dry Fluorescence Immunoassay)
85	TT Coagulation Analyzer Test Strip(Electrochemistry)
86	TT3 Test Kit(Dry Fluorescence Immunoassay)
87	TT4 Test Kit(Dry Fluorescence Immunoassay)
88	UA Test Kit(Dry Fluorescence Immunoassay)
89	β -HCG Test Kit(Dry Fluorescence Immunoassay)
90	25-OH-VD Control
91	25-OH-VD3 Control
92	AMH Control
93	B-HCG Control
94	BNP Control
95	CCP Control
96	CK-MB Control
97	CRP Control
98	cTnI Control
99	D-Dimer Control
100	Fer Control
101	FSH Control
102	HbA1c Control
103	HCY Control
104	H-FABP Control
105	IgG4 Control
106	IL-6 Control
107	LH Control
108	LP-PLA2 Control
109	MPO Control
110	Myo Control

111	NT-proBNP Control
112	P Control
113	PCT Control
114	PGI Control
115	PGII Control
116	PRL Control
117	S100- β Control
118	SAA Control
119	ST2 Control
120	TSH Control
121	TT3 Control
122	TT4 Control
123	(COVID-19) IgM/IgG Test Kit(Dry Fluorescence Immunoassay)
124	COVID-19 Antigen (Saliva) Test Kit(Dry Color Latex Immunoassay)
125	COVID-19 Antigen Control
126	COVID-19 Antigen Test Kit For Saliva(Dry Color Latex Immunoassay)
127	COVID-19 Antigen Test Kit(Dry Fluorescence Immunoassay)
128	COVID-19 Antigen Test Kit(Dry Color Latex Immunoassay)
129	COVID-19(Delta variant) Antigen Test Kit(Dry Fluorescence Immunoassay)
130	COVID-19(Delta variant)Antigen Test Kit(Dry Color Latex Immunoassay)
131	COVID-19 IgM/IgG/Neutralizing Antibody Control
132	Influenza A+B/COVID-19 Antigen Test Kit (Dry Color Latex Immunoassay)

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Attachment II

References to other union legislations, standards and common specification (if applicable) applied:

- 1) EN ISO13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes
- 2) EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- 3) EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- 4) ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 5) ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged - Products 150lb (68kg) or less)
- 6) ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer Information supplied by the manufacturer with medical devices
- 7) IEC 62366-1:2015+A1:2020 Medical Device Part 1 Application of usability engineering to medical devices
- 8) EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
- 9) EN ISO 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- 10) EN ISO 14155:2020 Clinical investigation of medical devices for human subjects — Good clinical practice
- 11) MEDDEV 2.7.1 Rev.4 GUIDELINES ON MEDICAL DEVICES
- 12) ASTM D4169 DC13 Standard Practice for Performance Testing of Shipping Containers and Systems