



EC Declaration of Conformity

In accordance with Directive 98/79/EC

Manufacturer: Zhejiang Anji Saianfu Biotech Co.,Ltd
2nd Floor, No 3 Factory, No 489 WenYun Road, TangPu Industrial Park, Dipu Subdistrict,
Anji county, 313303 HuZhou City, ZheJiang Province, China

No.	Product Name	Model
1	Adenovirus Ag Rapid Test	Cassette
2	Rotavirus and Adenovirus Combo Rapid Test	Cassette
3	COVID-19 Antigen Rapid Test	Cassette
4	COVID-19 IgG IgM Rapid Test	Cassette
5	COVID-19 Neutralization Antibody Detection Kit	Cassette
6	SARS-COV-2 & FLU A/B Antigen Rapid Test	Cassette
7	COVID-19/Flu A&B/RSV Ag Combo Rapid Test	Cassette
8	COVID-19 & FLU A/B & RSV & Adeno Antigen Rapid Test	Cassette
9	C-Reactive Protein Semi-Quantitative Rapid Test	Cassette
10	Cardiac Troponin T Rapid Test	Cassette
11	Dengue IgM/IgG Rapid Test	Cassette
12	Dengue NS1 Rapid Test	Cassette
13	Ferritin Rapid Test	Cassette
14	fFN Rapid Test	Cassette
15	FOB Rapid Test	Cassette
16	H.pylori Antibody Rapid Test	Cassette
17	H.pylori Antigen Rapid Test	Cassette
18	iGFBP-1 Rapid Test	Cassette
19	Influenza A/B Ag Rapid Test	Cassette
20	Malaria pf/pan Rapid Test	Cassette
21	Malaria pf/pv Rapid Test	Cassette
22	Mycobacterium Tuberculosis Rapid Test	Cassette
23	PSA Rapid Test	Cassette
24	Rotavirus Rapid Test	Cassette
25	RSV Ag Rapid Test	Cassette
26	Strep A Rapid Test	Cassette
27	Strep B Rapid Test	Cassette
28	Syphilis Antibody Rapid Test	Cassette
29	Torch Rapid Test	Cassette
30	Toxo IgG/IgM Rapid Test	Cassette



No.	Product Name	Model
31	Treponema Pallidum Antibody Rapid Test	Cassette
32	Troponin I Rapid Test	Cassette
33	Typhoid Antigen Rapid Test	Cassette
34	Typhoid IgG/IgM Rapid Test	Cassette
35	Pregnancy Rapid Test Midstream	Cassette/Strip/Midstream
36	AMP One Step Amphetamine Rapid Test	Cassette/Strip
37	BZO One Step Benzodiazepines Rapid Test	Cassette/Strip
38	COC One Step Cocaine Test Device	Cassette/Strip
39	K2 One Step Synthetic Cannabis Test	Cassette/Strip
40	MET One Step Methamphetamine Test	Cassette/Strip
41	MOP One Step Morphine Test	Cassette/Strip
42	THC One Step Marijuana Test	Cassette/Strip
43	One Step Multi-Drug Test Dip Card	Cassette
44	One Step Multi-Drug Test Urine Cupt	Cup

Conformity assessment route: Annex III (EC DECLARATION OF CONFORMITY)

Applicable Standards:

ISO 13485:2016

EN ISO 18113-3:2011

EN 13612:2002

ISO 14971:2019

EN 13641:2002

ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

We, the Manufacturer, herewith declare with sole responsibility that our products 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 hereby explicitly appoint **Lotus NL B.V. located at Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.** to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 20 /(Day)/ 8 /(Month) of 2020 /(Year).

Place Anji, Zhejiang, China

Represented by

Signature:

Name of authorized signatory: Wang Qin

Position held in the company: General Manager

Seal/Stamp:

