



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Hangzhou Tongzhou Biotechnology Co., Ltd.
Address: Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.
EC Representative: CMC Medical Devices & Drugs S.L.
Address: C/Horacio Lengo № 18
CP 29006, Málaga-Spain
Product Name: See attachments

Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Signature: 邵越水

Date: 2022.3.14

Name/ Position: 邵越水/ Vice General Manager

Place: Hangzhou / China

Attachment: Product List

No.	Product Description (产品名称)	CE Classification
1	Pregnancy (hCG) Rapid Test	Other
2	Pregnancy (hCG) Rapid Test (Urine)	Other
3	Pregnancy (hCG) Rapid Test Midstream	Other
4	Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	Other
5	Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	Other
6	Ovulation (LH) Rapid Test	Other
7	Ovulation (LH) Rapid Test Midstream	Other
8	FSH Rapid Test	Other
9	AMH Rapid Test	Other
10	Fetal Fibronectin (fFN) Rapid Test	Other
11	Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	Other
12	HSV 1/2 IgM Rapid Test (Serum/Plasma)	Other
13	HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
14	HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	Other
15	HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
16	HSV 1/2 IgG/IgM Combo Rapid Test	Other
17	Candida albicans Rapid Test	Other
18	Gonorrhea Rapid Test	Other
19	Gonorrhea and Chlamydia Combo Rapid Test	Other
20	Strep B Rapid Test	Other
21	Adenovirus Rapid Test	Other
22	Rotavirus Rapid Test	Other
23	Norovirus Rapid Test	Other
24	Rotavirus and Adenovirus Combo Rapid Test	Other
25	Norovirus, Rotavirus and Adenovirus Combo Rapid Test	Other
26	Astrovirus Rapid Test	Other
27	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	Other
28	Entamoeba histolytica Rapid Test	Other
29	Giardia Lamblia Rapid Test	Other
30	Cryptosporidium Rapid Test	Other
31	Cryptosporidium and Giardia Lamblia Combo Rapid Test	Other
32	Entamoeba/Giardia/Crypto Rapid Test (1 Window)	Other
33	Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	Other
34	Campylobacter Rapid Test	Other
35	Clostridium difficile GDH Rapid Test	Other
36	Clostridium difficile Toxin A +Toxin B Combo Rapid Test	Other
37	Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	Other
38	H. pylori Antibody Rapid Test (Serum/Plasma)	Other
39	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)	Other
40	H. pylori Antigen Rapid Test	Other
41	Vibrio cholerae O1 (VC O1) Rapid Test	Other
42	Vibrio cholerae O139 (VC O139) Rapid Test	Other
43	Vibrio cholerae O1/O139 Combo Rapid Test	Other
44	Chagas Rapid Test (Serum/Plasma)	Other
45	Chagas Rapid Test (Whole Blood/Serum/Plasma)	Other
46	Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	Other
47	Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
48	Dengue IgG/IgM Rapid Test	Other
49	Dengue NS1 Rapid Test	Other
50	Dengue IgG/IgM and NS1 Combo Rapid Test	Other
51	Zika NS1 Rapid Test	Other
52	Zika IgG/IgM Rapid Test	Other
53	Zika IgG/IgM and NS1 Combo Rapid Test	Other

54	Filariasis IgG/IgM Rapid Test (Serum/Plasma)	Other
55	Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
56	Typhoid IgG/IgM Rapid Test (Serum/Plasma)	Other
57	Typhoid IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
58	Salmonella typhi Antigen Rapid Test	Other
59	Leishmania IgG/IgM Rapid Test	Other
60	Leptospira IgG/IgM Rapid Test	Other
61	Malaria P.f. Rapid Test	Other
62	Malaria P.f./ Pan Rapid Test	Other
63	Malaria P.f./P.v. Rapid Test	Other
64	Malaria P.f./P.v. /Pan Rapid Test	Other
65	HEV IgG/IgM Rapid Test	Other
66	Syphilis Rapid Test	Other
67	Strep A Rapid Test (Control Line in Red)	Other
68	Strep A Rapid Test (Control Line in Blue)	Other
69	Streptococcus pneumoniae Antigen Rapid Test	Other
70	Mycoplasma pneumoniae Antigen Rapid Test	Other
71	Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test	Other
72	MONO Rapid Test	Other
73	Adenovirus pneumoniae Antigen Rapid Test	Other
74	Influenza A+B Rapid Test	Other
75	Influenza A Rapid Test	Other
76	RSV Rapid Test	Other
77	RSV&Influenza A+B Combo Rapid Test	Other
78	Adenovirus&RSV Combo Rapid Test	Other
79	Adenovirus, RSV and Influenza A+B Combo Rapid Test	Other
80	Brucella Abortus Antigen Rapid Test	Other
81	Lyme IgG/IgM Rapid Test	Other
82	Tetanus Rapid Test	Other
83	Tuberculosis (TB) Rapid Test	Other
84	7-Aminoclonazepam (7-ACL) Rapid Test	Other
85	Amphetamine (AMP) Rapid Test	Other
86	Barbiturate (BAR) Rapid Test	Other
87	Buprenorphine (BUP) Rapid Test	Other
88	Benzodiazepines (BZO) Rapid Test	Other
89	Cocaine (COC) Rapid Test	Other
90	Cotinine (COT) Rapid Test	Other
91	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test	Other
92	Ethyl Glucuronide (ETG) Rapid Test	Other
93	Fentanyl (FYL) Rapid Test	Other
94	Ketamine (KET) Rapid Test	Other
95	Ecstasy (MDMA) Rapid Test	Other
96	Methamphetamine (MET) Rapid Test	Other
97	Morphine (MOP) Rapid Test	Other
98	Methylphenidate (MPD) Rapid Test	Other
99	Methadone (MTD) Rapid Test	Other
100	Opiates (OPI) Rapid Test	Other
101	Oxycodone (OXY) Rapid Test	Other
102	Phencyclidine (PCP) Rapid Test	Other
103	Synthetic Marijuana (K2) Rapid Test	Other
104	Tricyclic Antidepressants (TCA) Rapid Test	Other
105	Marijuana (THC) Rapid Test	Other
106	Zolpidem (ZOL) Rapid Test	Other
107	Zopiclone (ZOP) Rapid Test	Other
108	Multi-Drug Rapid Test	Other
109	Multi-Drug Rapid Test 1-Step Cup	Other
110	Multi-Drug Rapid Test Key Cup	Other
111	AFP Rapid Test	Other

112	CEA Rapid Test	Other
113	CA125 Rapid Test	Other
114	CA15-3 Rapid Test	Other
115	CA19-9 Rapid Test	Other
116	FOB Rapid Test	Other
117	Calprotectin and FOB Combo Rapid Test	Other
118	Transferrin and FOB Combo Rapid Test	Other
119	Hb+Hb-Hp Combo Rapid Test	Other
120	Cardiac Troponin I (cTnI) Rapid Test	Other
121	Cardiac Troponin T (cTnT) Rapid Test	Other
122	CK-MB Rapid Test	Other
123	Myoglobin Rapid Test	Other
124	H-FABP Rapid Test	Other
125	H-FABP and cTnI Combo Rapid Test	Other
126	Myoglobin/CK-MB/Troponin I Combo Rapid Test	Other
127	H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	Other
128	NT-proBNP Rapid Test	Other
129	D-dimer Rapid Test	Other
130	C-reactive protein Rapid Test	Other
131	C-reactive protein Semi-Quantitative Rapid Test	Other
132	Procalcitonin (PCT) Rapid Test (Serum/Plasma)	Other
133	Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)	Other
134	Ferritin Rapid Test	Other
135	Ferritin Semi-Quantitative Rapid Test	Other
136	SP-10 Male Fertility Rapid Test	Other
137	TSH Rapid Test	Other
138	Vitamin D Rapid Test	Other
139	HbA1c Rapid Test	Other
140	Blood Stain Rapid Test	Other
141	Human Semen Rapid Test	Other
142	Calprotectin Rapid Test	Other
143	Lactoferrin Rapid Test	Other
144	Calprotectin and Lactoferrin Combo Rapid Test	Other
145	IgE Rapid Test	Other
146	Rheumatoid Factor Rapid Test	Other
147	Micro-Albumin Semi-Quantitative Rapid Test	Other
148	Micro-Albumin Qualitative Rapid Test	Other
149	SAA Rapid Test	Other
150	SAA and CRP Combo Rapid Test	Other



Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Holder of Certificate: **Hangzhou Tongzhou Biotechnology Co., Ltd.**

Room 102, Building 4, No. 191, Xintian Road, Yunhe Street
Linping District
311103 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases, including Professional Laboratory Use, Near Patient and Self Testing

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120095 0001 Rev. 00

Report No.: SH23211001

Valid from: 2023-07-20

Valid until: 2026-07-19

Date, 2023-07-21

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 120095 0001 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **Hangzhou Tongzhou Biotechnology Co., Ltd.**
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street,
Linping District, 311103 Hangzhou, Zhejiang Province, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate

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