



# DECLARATION OF CONFORMITY

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

**Manufacturer:** ShenZhen GangZhu Medical Technology Co.,Ltd

**Address:** B1219-1232, Building 2, Skyworth innovation Valley,  
No.8, Tangtou 1 Road, Tangtou community, Shiyan  
Street, Baoan District, ShenZhen city, China

**Product Name:** Real-time Fluorescence PCR Instrument Model:  
GZ-8Plus  
Automated Nucleic Acid Extractor Model: GZ-NP2  
Detection Kit (See Attachment)

**Specification:** See Attachment

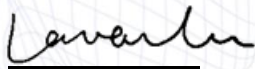
**Classification:** Others (IVDD)

**Conformity Assessment** Annex III of In Vitro Diagnostic Directive (98/79/EC)

**Procedure:**

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

EN ISO 14971:2019	EN ISO 18113-2:2011	EN ISO 23460:2015
EN ISO 18113-1:2011	EN ISO 13612:2022+AC:2022	EN 13641:2022
EN ISO 20417:2021	EN ISO 15223-1:2021	

Signature:   
Position: International Sales manager  
Date: 2022.04.01  
Place: CHINA

## Attachment

No.	Cat No.	Product Name	Specification
1	GZP001	$\alpha$ Coronavirus type I Real Time PCR Detection Kit	8 Tests/Kit
2	GZP004	Feline Parvovirus Real Time PCR Detection Kit	8 Tests/Kit
3	GZP020	Canine Parvovirus Real Time PCR Detection Kit	8 Tests/Kit
4	GZP002	Feline Calicivirus Real Time PCR Detection Kit	8 Tests/Kit
5	GZP003	Feline Herpesvirus type I Real Time PCR Detection Kit	8 Tests/Kit
6	GZP014	Chlamydia Real Time PCR Detection Kit	8 Tests/Kit
7	GZP025	Mycoplasma Real Time PCR Detection Kit	8 Tests/Kit
8	GZP005	Toxoplasma gondii Real Time PCR Detection Kit	8 Tests/Kit
9	GZP006	Heartworm Real Time PCR Detection Kit	8 Tests/Kit
10	GZP007	Leptospira spp. Real Time PCR Detection Kit	8 Tests/Kit
11	GZP008	Borrelia burgdorferi Real Time PCR Detection Kit	8 Tests/Kit
12	GZP016	Canine Adenovirus type I Real Time PCR Detection Kit	8 Tests/Kit
13	GZP017	Canine Adenovirus type II Real Time PCR Detection Kit	8 Tests/Kit
14	GZP018	Canine Parainfluenza Virus Real Time PCR Detection Kit	8 Tests/Kit
15	GZP019	Canine Distemper Virus Real Time PCR Detection Kit	8 Tests/Kit
16	GZP021	Babesia spp. Real Time PCR Detection Kit	8 Tests/Kit
17	GZP022	Giardia lamblia Real Time PCR Detection Kit	8 Tests/Kit

18	GZP024	Cryptosporidium spp. Real Time PCR Detection Kit	8 Tests/Kit
19	GZP027	Ehrlichia spp. Real Time PCR Detection Kit	8 Tests/Kit
20	GZP028	Feline Immunodeficiency Virus Real Time PCR Detection Kit	8 Tests/Kit
21	GZP029	Feline Leukemia Virus Real Time PCR Detection Kit	8 Tests/Kit
22	GZP037	Brucella spp. Real Time PCR Detection Kit	8 Tests/Kit
23	GZP039	Bordetella bronchiseptica Real Time PCR Detection Kit	8 Tests/Kit
24	GZP040	Rabies Virus Real Time PCR Detection Kit	8 Tests/Kit
25	GZP041	Tritrichomonas foetus Real Time PCR Detection Kit	8 Tests/Kit
26	GZP048	Helicobacter pylori Real Time PCR Detection Kit	8 Tests/Kit
27	GZP061	Leishmania spp. Real Time PCR Detection Kit	8 Tests/Kit
28	GZP062	Hemotropic mycoplasmas Real Time PCR Detection Kit	8 Tests/Kit
29	GZP067	Anaplasma spp. Real Time PCR Detection Kit	8 Tests/Kit
30	GZP070	Neospora caninum Real Time PCR Detection Kit	8 Tests/Kit
31	GZP074	Influenza A Virus Real Time PCR Detection Kit	8 Tests/Kit
32	GZP075	Canine Herpesvirus 1 Real Time PCR Detection Kit	8 Tests/Kit
33	GZP076	Canine respiratory coronavirus Real Time PCR Detection Kit	8 Tests/Kit
34	GZP077	Canine Pneumovirus Real Time PCR Detection Kit	8 Tests/Kit
35	GZP030	Feline Calicivirus / Feline Herpesvirus type I Real Time PCR Detection Kit	8 Tests/Kit

36	GZP032	Chlamydia / Mycoplasma Real Time PCR Detection Kit	8 Tests/Kit
37	GZP031	Parvovirus / $\alpha$ Coronavirus type I Real Time PCR Detection Kit	8 Tests/Kit
38	GZP034	Leptospira spp. / Toxoplasma gondii Real Time PCR Detection Kit	8 Tests/Kit
39	GZP036	Babesia canis / Babesia gibsoni Real Time PCR Detection Kit	8 Tests/Kit
40	GZP042	Feline Immunodeficiency Virus / Feline Leukemia Virus Real Time PCR Detection Kit	8 Tests/Kit
41	GZP043	Bartonella henselae / Toxoplasma gondii Real Time PCR Detection Kit	8 Tests/Kit
42	GZP046	Giardia lamblia / Tritrichomonas foetus Real Time PCR Detection Kit	8 Tests/Kit
43	GZP073	Cryptosporidium spp. / Helicobacter pylori Real Time PCR Detection Kit	8 Tests/Kit
44	GZP079	Canine Distemper Virus / Canine Parainfluenza Virus Real Time PCR Detection Kit	8 Tests/Kit
45	GZP054	Feline Stomatitis Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
46	GZP055	Feline Anemia Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
47	GZP052	Canine Respiratory Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
48	GZP053	Canine Gastrointestinal Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
49	GZP038	Feline Respiratory Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit

50	GZP047	Feline Gastrointestinal Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
51	GZP051	Canine Blood Parasites Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
52	GZP072	New Canine Blood Parasites Panel (4 items) Real Time PCR Detection Kit	8 Tests/Kit
53	GZP045	Feline Respiratory Panel (5 items) Real Time PCR Detection Kit	8 Tests/Kit
54	GZP049	Zoonosis Panel (6 items) Real Time PCR Detection Kit	8 Tests/Kit
55	GZP050	Canine Anemia Panel (6 items) Real Time PCR Detection Kit	8 Tests/Kit
56	GZP078	Canine Respiratory Panel (6 items) Real Time PCR Detection Kit	8 Tests/Kit
57	GZEP001	Parrot Bornavirus Real Time PCR Detection Kit	8 Tests/Kit
58	GZEP002	Parrot Beak And Feather Disease Virus Real Time PCR Detection Kit	8 Tests/Kit
59	GZEP003	Avian Polyomavirus Real Time PCR Detection Kit	8 Tests/Kit
60	GZEP004	Chlamydia psittaci Real Time PCR Detection Kit	8 Tests/Kit
61	GZEP005	Psittacid Herpesvirus Real Time PCR Detection Kit	8 Tests/Kit
62	GZEP006	Pigeon Paramyxovirus Real Time PCR Detection Kit	8 Tests/Kit
63	GZEP008	Trichomonas gallinae Real Time PCR Detection Kit	8 Tests/Kit
64	GZEP009	Pigeon Circovirus Real Time PCR Detection Kit	8 Tests/Kit

65	GZEP018	Pigeon Adenovirus type 1 Real Time PCR Detection Kit	8 Tests/Kit
66	GZEP019	Pigeon Adenovirus type 2 Real Time PCR Detection Kit	8 Tests/Kit
67	GZEP010	Parrot Beak And Feather Disease Virus / Avian Polyomavirus Real Time PCR Detection Kit	8 Tests/Kit
68	GZEP011	Rabbit Encephalitozoon cuniculi Real Time PCR Detection Kit	8 Tests/Kit
69	GZEP012	Rabbit Hemorrhagic Disease Virus Real Time PCR Detection Kit	8 Tests/Kit
70	GZEP013	Mink Enteritis Virus Real Time PCR Detection Kit	8 Tests/Kit
71	GZEP014	Mink Distemper Virus Real Time PCR Detection Kit	8 Tests/Kit
72	GZEP015	Aleutian Mink Disease Virus Real Time PCR Detection Kit	8 Tests/Kit
73	GZEP016	Chelonid Alpha Herpesvirus Real Time PCR Detection Kit	8 Tests/Kit
74	GZEP017	Mycoplasma agassizii Real Time PCR Detection Kit	8 Tests/Kit
75	GZEP020	Snake Paramyxovirus Real Time PCR Detection Kit	8 Tests/Kit
76	GZEP021	Cryptosporidium serpentis / Cryptosporidium saurophilum Real Time PCR Detection Kit	8 Tests/Kit
77	GZEP022	Cryptosporidium saurophilum Real Time PCR Detection Kit	8 Tests/Kit