EC Declaration of Conformity

according to Directive 98/79/EC, on in vitro diagnostic medical devices

Ref. No.:20220513-F02

Manufacturer
(Name, Address)

Getein Biotech, Inc.
No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative
(Name, Address)

CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Medical device

No.	Product Name
1	Myo Control
2	CK-MB Control
3	NT-proBNP Control
4	D-Dimer Control
5	PCT Control
6	CRP Control
7	cTnI Control
8	H-FABP Control
9	mAlb Control
10	NGAL Control
11	β_2-MG Control
12	CysC Control
13	CK-MB/cTnI/Myo Control
14	CK-MB/cTnI Control
15	NT-proBNP/cTnI Control
16	HCG+β Control
17	HbA1c Control
18	TSH Control
19	T4 /T3 Control
20	T3 Control
21	T4 Control

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Location: Moldova

22	FOB Control
23	H. pylori Control
24	SAA Control
25	LH Control
26	FSH Control
27	25-OH-VD Control
28	fT3 Control
29	fT4 Control
30	PRL Control
31	SARS-CoV-2 Control
32	Prog Control
33	IL-6 Control
34	Fer Control
35	cTnT Control
36	BNP Control
37	IGE Control
38	AMH Control
39	TPO Control
40	TG-Ab Control
41	T Control
42	E2 Control
43	E3 Control
44	HCG+β Control
45	CA50 Control
46	CA125 Control
47	CA15-3 Control
48	CA19-9 Control
49	CA242 Control
50	CA72-4 Control
51	CY21-1 Control
52	NSE Control

53	AFP Control
54	CEA Control
55	Fer Control
56	HE4 Control
57	cTnT Control
58	INS Control
59	C-P Control
60	PTH Control
61	BGP Control
62	IAA Control
63	IgE Control
64	GH Control
65	Cor Control
66	TP Control
67	PGI Control
68	PGII Control
69	G17 Control
70	Pro-GRP Control
71	SCC Control
72	ST2 Control
73	PLA2 Control
74	CG Control
70	HA Control
71	LN Control
72	III Control
73	CIV Control
74	SHBG Control
75	Renin Control
76	TG Control
77	PVK Control
78	HBP Control

79	PIIIP N-P Control
80	CIV Control
81	CRP Calibrator
82	β2-MG Calibrator
83	C3 Calibrator
84	C4 Calibrator
85	IgA Calibrator
86	CysC Calibrator
87	IgG Calibrator
88	IgM Calibrator
89	PA Calibrator
90	ApoA1 Calibrator
91	ApoB Calibrator

Classification	Other device (according to Annex II of the directive 98/79/EC)		
Conformity assessment route	Annex III of the 98/79/EC		
Applicable coordination standards	EN 13612:2002	EN ISO 14971:2019	EN ISO15223-1:2016
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 18113-3:2011
	EN ISO 23640:2015	EN ISO 13485:2016	ISO 780:2015

Signatory representative declares herein the above-mentioned device meets the basic requirements of the European Parliament and the Council's in vitro diagnostic medical devices directive: 98/79/EC Annex I.

This declaration of conformity is based on European Parliament and the Council's 98/79/EC directive Annex III. The compiled technical file and quality system document according to 98/79/EC directive Annex III are testified and the quality system certificate has issued by BSI Group The Netherlands B. V. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing, 13th may 2022

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)

CE