

# Declaration of Conformity

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

Ref. No.:20210201-A01

<b>Maker</b> (Name, Address)	<b>Getein Biotech, Inc.</b> No. 9 Bofu Road, Luhe District, Nanjing, 211505, China	
<b>Authorized Representative</b> (Name, Address)	<b>Lotus NL B.V.</b> Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.	
<b>Medical device</b>	<b>Category</b>	<b>Product Name</b>
	<b>Instrument</b>	Getein1100 Immunofluorescence Quantitative Analyzer Getein1180 Immunofluorescence Quantitative Analyzer Getein1600 Immunofluorescence Quantitative Analyzer
	<b>Cardiac Markers</b>	Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) BNP Fast Test Kit (Immunofluorescence Assay) NT-proBNP Fast Test Kit (Immunofluorescence Assay) NT-proBNP/cTnI Fast Test Kit (Immunofluorescence Assay) NT-proBNP/NGAL Fast Test Kit(Immunofluorescence Assay) CK-MB Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) CK-MB/cTnI/H-FABP Fast Test Kit (Immunofluorescence Assay) H-FABP Fast Test Kit (Immunofluorescence Assay) Lp-PLA2 Fast Test Kit (Immunofluorescence Assay) HCY Fast Test Kit (Immunofluorescence Assay ) S100-β Fast Test Kit (Immunofluorescence Assay) ST2 Fast Test Kit (Immunofluorescence Assay)
	<b>Coagulation Markers</b>	D-Dimer Fast Test Kit (Immunofluorescence Assay)
	<b>Diabetes Mellitus</b>	HbA1c Fast Test Kit (Immunofluorescence Assay)
	<b>Inflammation</b>	PCT Fast Test Kit (Immunofluorescence Assay) PCT/CRP Fast Test Kit (Immunofluorescence Assay) hs-CRP+CRP Fast Test Kit (Immunofluorescence Assay) SAA Fast Test Kit (Immunofluorescence Assay)

<b>Renal Function</b>	SAA/CRP Fast Test Kit (Immunofluorescence Assay)
	IL-6 Fast Test Kit (Immunofluorescence Assay)
	CysC Fast Test Kit (Immunofluorescence Assay)
	mAlb Fast Test Kit (Immunofluorescence Assay)
	NGAL Fast Test Kit (Immunofluorescence Assay)
	Scr Fast Test Kit (Immunofluorescence Assay )
	$\beta$ 2-MG Fast Test Kit (Immunofluorescence Assay)
<b>Thyroid Function</b>	TSH Fast Test Kit (Immunofluorescence Assay)
	T3 Fast Test Kit (Immunofluorescence Assay)
	T4 Fast Test Kit (Immunofluorescence Assay)
	fT3 Fast Test Kit (Immunofluorescence Assay)
	fT4 Fast Test Kit (Immunofluorescence Assay)
<b>Reproduction/ Fertility</b>	HCG+ $\beta$ Fast Test Kit (Immunofluorescence Assay)
	PLGF Fast Test Kit(Immunofluorescence Assay )
	LH Fast Test Kit (Immunofluorescence Assay)
	FSH Fast Test Kit (Immunofluorescence Assay)
	AMH Fast Test Kit (Immunofluorescence Assay)
	PRL Fast Test Kit (Immunofluorescence Assay)
	Testosterone Fast Test Kit (Immunofluorescence Assay)
	E2 Fast Test Kit (Immunofluorescence Assay)
Prog Fast Test Kit (Immunofluorescence Assay)	
<b>Tumor Markers</b>	AFP Fast Test Kit (Immunofluorescence Assay)
	CEA Fast Test Kit (Immunofluorescence Assay)
	CA125 Fast Test Kit (Immunofluorescence Assay)
	CA19-9 Fast Test Kit (Immunofluorescence Assay)
	CA15-3 Fast Test Kit (Immunofluorescence Assay)
	AFP/CEA Fast Test Kit (Immunofluorescence Assay)
<b>Stomach function</b>	PG I /PG II Fast Test Kit (Immunofluorescence Assay)
	H. pylori Fast Test Kit (Immunofluorescence Assay)
	FOB Fast Test Kit (Immunofluorescence Assay)
<b>Infectious Disease</b>	Anti-TP Fast Test Kit (Immunofluorescence Assay)
	RSV/Influenza A/B Fast Test Kit (Immunofluorescence Assay)
	Influenza A/B Fast Test Kit (Immunofluorescence Assay)
	RSV Fast Test Kit (Immunofluorescence Assay)
	Novel Coronavirus (2019-nCoV) IgM/IgG antibody Fast Test kit (Immunofluorescence Assay)
	SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay)



	SARS-CoV-2 Total Antibody/Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)
	SARS-CoV-2 Neutralizing Antibody Fast Test Kit (Immunofluorescence Assay)
	FluA/FluB/SARS-CoV-2 Antigen Fast Test Kit (Immunofluorescence Assay)
<b>Rheumatism series</b>	Total IgE Fast Test Kit (Immunofluorescence Assay)
	RF Fast Test Kit (Immunofluorescence Assay)
	anti-CCP Fast Test Kit (Immunofluorescence Assay )
	ASO Fast Test Kit (Immunofluorescence Assay)
<b>Metabolic Markers</b>	25-OH-VD Fast Test Kit (Immunofluorescence Assay)
	Vit-B12 Fast Test Kit (Immunofluorescence Assay)
	Transferrin Fast Test Kit (Immunofluorescence Assay)
	Folate acid Fast Test Kit (Immunofluorescence Assay)
	Ferritin Fast Test Kit (Immunofluorescence Assay)

**Classification** Others

<b>Applicable coordination standards</b>	EN 13612:2002	EN ISO 14971:2012	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
	EN 61326-2-6:2006	IEC 61326-1:2013	
	EN 61010-2-101:2002	IEC 61010-1:2010	

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 III. 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..

**General Manager** Enben Su

Nanjing, 1<sup>st</sup> Feb. 2021  
(place and date of issue)

*Enben Su*  
  
 (name and signature or equivalent marking of authorized person)

