Declaration of Conformity

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

Ref. No.:20210124-A01

Maker (Name, Address)	**Getein Biotech, Inc.** No. 9 Bofu Road, Luhe District, Nanjing, 211505, China
Authorized Representative (Name, Address)	**Lotus NL B.V.** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

	Product Name	**GMDN Code**
Medical device	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	64756
	One Step Test for SARS-Cov-2 Antigen (Colloidal Gold)	64787

Classification Others

Applicable coordination standards	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

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, 24th Jan. 2021
(place and date of issue)

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

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