Declaration of Conformity

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

Ref. No.:20201103-B01

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.
Medical device	**Product Name**: One Step Test for SARS-Cov-2 Antigen (Colloidal Gold) — **GMDN Code**: 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, 3th Nov, 2020
(place and date of issue)

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

CE