CERTIFICATE

EC Certificate No. 1434-IVDD-447/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

GETEIN Biotech, Inc.

Nanjing, ul. Bofu Road, Luhe District 9, China

in vitro diagnostic medical devices
for self-testing

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

Ref. codes: CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159, CG2061510, CG2061512, CG2061515, CG2061520, CG2061525

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021

CE 1434

Issued under the Contract No. MD-66/2021
Application No: 142/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Vice-President

Declaration of Conformity

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

Ref. No.:20210816-A01

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

	Product Name	**GMDN Code**
Medical device	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)	65454

Catalogue number	CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159, CG2061510, CG2061512, CG2061515, CG2061520, CG2061525
Classification	Self-testing (according to Article 1 (d) of 98/79/EC)
Conformity assessment route	Annex III section 6 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 18113-4-2011
EN ISO 23640:2013	EN ISO 13485:2016	EN ISO 780: 2015
EN 62366:2008	EN 13641:2002	EN 980:2008
EN 13975:2003	EN 13532:2002	

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, the EC certificate has issued by Polish Centre for Testing and Certification. The manufacturer is exclusively responsible for the declaration of conformity.

General Manager Enben Su

Nanjing, 16th Aug, 2021

(place and date of issue)

Enben Su

(name and signature or equivalent marking of authorized person)