

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 N° 18, CP 29006, Málaga, Spain

Medical device **Product Name** **GMDN Code**
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)


(name and signature or equivalent marking of authorized person)



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



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