

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

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Issued under the Contract No. MD-66/2021

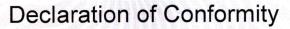
Application No: 142/2021

Certificate bears the qualified signature.

Warsaw, 30.07.2021

Module A1

Vice-President



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

Ref. No.:20210816-A01

Manufacturer

Getein Biotech, Inc.

(Name, Address)

No. 9 Bofu Road, Luhe District, Nanjing, 211505, China

Authorized Representative

CMC Medical Devices & Drugs S.L.

(Name, Address)

Add: C/ Horacio Lengo Nº 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

EN 13612:2002

EN ISO 14971:2019

EN ISO15223-1:2016

coordination

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

standards

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.

Enben Su General Manager

(place and date of issue)

(name and signature or equivalent marking of authorized person)