EC Declaration of Conformity

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

Ref. No.:20211130-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	
EC certificate no.	1434-IVDD-447/2021	**Validity of the Certificate** 30.07.2021-27.05.2024

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, and the quality system certificate has issued by BSI Group The Netherlands B. V.. The manufacturer is exclusively responsible for the EC declaration of conformity.

General Manager Enben Su

Nanjing. Nov. 30, 2021

(place and date of issue)

(name and signature or equivalent marking of authorized person)

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