EC declaration of conformity

CE

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

Manufacturer: Xiamen Wiz Biotech CO.,LTD.

Address: 3-4 Floor,NO.16 Building,Bio-medical Workshop,2030 Wengjiao West Road,Haicang District,361026,Xiamen,China

EC REP **EU representative:** WellKang Ltd

Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: Diagnostic Kit (Colloidal Gold）for IgG/IgM Antibody to SARS-CoV-2

Product Type: 1 Test/kit, 5 Tests/kit, 20 Tests/kit, 25 Tests/kit

Product Classification: Other IVD Device (Route: IVDD98/79/EC Annex III)

Hereby declare under the sole responsibility of the manufacturer that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:

In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.

Standards we are implementing:

EN 13612:2002/AC:2002	*EN ISO 13485:2016*	*EN ISO 14971:2012*
EN ISO 23640:2015	*EN 13641:2002*	*EN ISO 15223-1:2016*
EN ISO 18113-1:2011	*EN ISO 18113-2:2011*	

Xiamen Wiz Biotech CO.,LTD.

XiaMen. China	May 8, 2020	Xiaozhen Wang,	General Manager
Place	*date*	*Signature,*	*Title*