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 Xi Road, Haicang District, Xiamen City, Fujian Province, 361026, P.R.China

EC REP **EU Representative:** WellKang Ltd

Address: Enterprise Hub, NW Business Complex,1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland,UK.

Product Name: SARS-CoV-2 Antigen Rapid Test

Product Type: 1 Test/kit, 2 Tests/kit, 3Tests/kit, 5 Tests/kit, 10Tests/kit, 20Tests/kit, 25Tests/kit, 30Tests/kit, 40Tests/kit, 50Tests/kit, 100Tests/kit, 200Tests/kit

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

We hereby state 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 **October 21, 2020** **General Manager**

Place ***date*** ***Signature,*** ***Title***