

# EC declaration of conformity

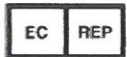


According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device



**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



**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 October 1998 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

Place      date

*Wang*  
Signature,

General Manager

Title