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

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*	

厦门世正生物科技股份有限公司

Xiamen Wiz Biotech CO., LTD.

XiaMen. China **August 10, 2020**

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

Certificate CN19/42110

The management system of

Xiamen Wiz Biotech Co., Ltd.

3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road,
Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of in vitro diagnostic medical devices including hormone marker test kit, kidney disease marker test kit, tumor marker test kit, infectious disease marker test kit, gastrointestinal inflammation marker test kit, cardiac marker test kit, immunochromatography analyzer.

This certificate is valid from 4 September 2019 until 3 September 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 July 2022
Issue 1. Certified since 4 September 2019

Authorised by

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HC SGS 13485 2016 0118

European Commission

Internal Market, Industry, Entrepreneurship and SMEs

Notification

Found : 0

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Notified Body number : 0120

Version(s): 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 **22**

Last approval date : 02/10/2020

Legislations

No data selected

Statement for the detection of the S glycoprotein mutant strain

Spike glycoprotein exist on the surface of novel coronavirus and easily mutated such as HV69-70 missing, Y144 missing, N501Y, A570D, D614G, P681H, T716I, S982A, D1118H , B-117 ,B-1351 and so on.

The viral nucleocapsid is composed of nucleocapsid protein (N protein for short) and RNA. The N protein is relatively stable, the largest proportion in viral structural proteins and high sensitivity in detection.

Based on the features of N protein, Monoclonal antibody of N protein against novel coronavirus was chosen in the development and design of our product named 'SARS-CoV-2 Antigen Rapid Test' that is intended for the qualitative detection of SARS-CoV-2 Antigen in oropharyngeal swab and nasopharyngeal swab specimens in vitro through the detection of N protein.

That is to say, the current spike glycoprotein mutant strain including UK variant (B-117) and South Africa(B-1351) are not affected by detection.

XIAMEN WIZ BIOTECH CO.,LTD

2021.02.17

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