

EC declaration of conformity

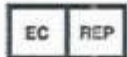


According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device



Manufacturer: Xiamen Wiz Biotech CO., LTD.

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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

Xiamen Wiz Biotech CO., LTD.

XiaMen. China August 10, 2020

Place date



SARS-CoV-2 Antigen Rapid Test

Clinical report summary

- Comparative analysis of test reagent results with PCR test results

The detection results of test reagent and the PCR test results were shown in the following table:

		PCR test results		Total
		Positive (+)	Negative (-)	
Test reagent results	Positive (+)	78	0	78
	Negative (-)	3	257	260
Total number		81	257	338

Sensitivity: 96.3%; (95%CI: 89.67%~98.73%)

Specificity:100 %; (95%CI: 98.53%~100%)

Total clinical coincidence rate:99.11%. (95%CI: 97.42%~99.70%)

The above results showed that there was no statistically significant difference between the detection reagent and the PCR results。