



EC Declaration of Conformity

Manufacturer 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

European Representative Qarad EC-REP BV
Pas 257, 2440 Geel, Belgium

Product SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

Model 1 test/kit, 2 tests/kit, 5 tests/kit, 10 tests/kit.

Catalogue number 51332801, 51332802, 51332803, 51332804

Classification Self-Test

Conformity assessment route Annex III including Section 6

We, the manufacturer, herewith, declares that the product(s) as specified above meet(s) the applicable provisions of the European Directive 98/79/EC on *in vitro* Diagnostic Medical Devices. All supporting technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the Authorized Representative in Europe.

General applicable directive:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Notified Body: Polish Centre for Testing and Certification

Identification number: CE1434

EC Certificate No.: 1434-IVDD-492/2021

Start of CE Marking: 2021-11-22

Signed on 22/(Day) 11/(Month) of 2021. Place Xiamen.

Represented by

Signature:

Name of authorized signatory: Xiaozhen Wang

Position held in the company: General Manager

Seal/Stamp:

