



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 Type A: 1 test/kit, 2 tests/kit, 5tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit.
Type B: 1 test/kit, 2 tests/kit, 5tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit.

Catalogue number 51232801, 51232803, 51232809, 51232811, 51232805, 51232807
51232802, 51232804, 51232810, 51232812, 51232806, 51232808

Classification Others

Conformity assessment route: Annex III (IVDD 98/79 EC)


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.

Signed on 10/(Day) 03/(Month) of 2021. Place Xiamen.

Represented by

Signature: 
Name of authorized signatory: Xiaozhen Wang
Position held in the company: General Manager

Seal/Stamp:

