CE

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, 20 tests/kit, 25 tests/kit. Type B: 1 test/kit, 2 tests/kit, 20 tests/kit, 25 tests/kit.
Catalogue number	51232801, 51232803, 51232805, 51232807 51232802, 51232804, 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 05 /(Day) 02 /(Month) of 2021 . Place Xiamen .

Represented by

Signature:

Seal/Stamp:

厦门为正生物科技股份有限公司 3502056028897

Name of authorized signatory: Xiaozhen Wang

Position held in the company: General Manager