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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

Qarad EC-REP BV

Representative 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 .

