



Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Maccura Biotechnology Co., Ltd.*

Legal Manufacturer Address: *16#, Baichuan Road, Hi-tech Zone, 611731, Chengdu
PEOPLE' S REPUBLIC OF CHINA*

Declares, that the products
Product Name

Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2)
IgM/IgG Antibody Assay Kit by Colloidal Gold Method

Classification: *Others*
Conformity assessment route: *Annex III, except section 6*

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentation is retained at the premise of the manufacturer.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg. Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: 2020-03-05


Name of authorized signatory: Mingjian Wu
Position held in the company: General Manager

Declaration of Conformity

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16#, Baichuan Road, Hi-tech Zone, 611731 Chengdu, PEOPLE'S REPUBLIC OF CHINA

European Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Information SARS-CoV-2 Fluorescent PCR

Classification Others

Conformity Assessment Route Annex III, except section 6

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentation is retained at the premise of the manufacturer.

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

Start of CE-MARK 2020-03-05

Place, Date of issue

Chengdu, 2020-03-05

Signature



maccura