

CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Zhejiang GENE SCIENCE Co., Ltd

Address: No. 2 workshop, pharmaceutical industrial park, no. 11 shengxing road, shangyu economic and technological development zone, shaoxing, zhejiang, China.

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

In Vitro Diagnostic Directive:

- ◆ Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

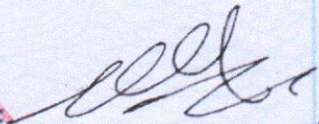
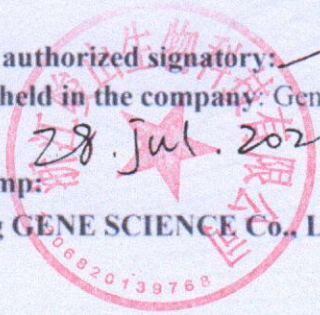
ISO 13485:2016	EN ISO 18113-3:2011	EN 13612:2002
ISO 14971:2019	EN 13641:2002	ISO 23640:2015
EN ISO 18113-1:2011	ISO 15223-1:2016	EN 62366-1:2015
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed: 张锋

Place: Shaoxing, China.

Name of authorized signatory: 
Position held in the company: General Manager
Date: 28 Jul. 2020
Seal/Stamp: 
Zhejiang GENE SCIENCE Co., Ltd