CE

DECLARATION OF CONFORMITY

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

Manufacturer: Nanjing Synthgene Medical Technology Co., Ltd.

Address: No. 9 Weidi Road, Qixia District, Nanjing City, Jiangsu Province ,P.R.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:

- SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit(Colloidal gold method)

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 on: Kun Tong

Place: Nanjing,China

Name of authorized signatory:

Position held in the company: General Manager

Date: 2020.4.20

Seal/Stamp:

Nanjing Synthgene Medical Technology Co., Ltd.