



## 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*

*ISO 14971:2019*

*EN ISO 18113-1:2011*

*EN ISO 18113-2:2011*

*EN ISO 18113-3:2011*

*EN 13641:2002*

*ISO 15223-1:2016*

*EN 13612:2002*

*ISO 23640:2015*

*EN 62366-1:2015*

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.**