

# Declaration of Conformity

Certificate No.:EU2021077

**Manufacturer:**

Genrui Biotech Inc.

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**European Representative:**

Lotus NL B.V.

Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.

**Product Name:**

SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

**Model:**

1T/kit, 5T/kit, 10T/kit, 20T/kit, 25T/kit, 50T/kit

**Classification:**

Others (not in List A and List B).

**Conformity Assessment Route:**

IVDD 98/79/EC Annex III (excludes section 6)

We herewith declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

**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.

**Standards Applied:**

EN ISO 13485:2016

EN ISO 23640:2015

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 15223-1:2016

EN 13612:2002

EN ISO 18113-2:2011



Place, Date of Issue:

Shenzhen, Mar. 9<sup>th</sup>, 2021

Position Held in Company:

Management Representative

Signature:

