

Declaration of Conformity

Manufacturer:

Genrui Biotech Inc.

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European Representative:

Lotus NL B.V.

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

Product Name:

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

Model:

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

Classification:

Others device, not in annex II and not for self-testing, not for performance evaluation.

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, Oct. 13th, 2020

Position Held in Company:

Management Representative

Signature: