

Declaration of Conformity

Certificate No.:EU2020046

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 ISO 18113-2:2011	EN 13612:2002	IEC61326-1:2012
IEC61326-2-6:2012	IEC61010-2-101:2015	IEC61010-2-081:2015	IEC61010-1:2010



Place, Date of Issue: Shenzhen, Nov.9th, 2020
Position Held in Company: Management Representative
Signature:

5.1.2e