


Genrui

≡ **Declaration of Conformity** ≡

Manufacturer:

Genrui Biotech Inc.

4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

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Fax: +86 755 26678789

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)

Specification: 1 T/kit, 5 T/kit, 25 T/kit**REF:** 52104097, 52112086, 52026094**Classification:**

Self-testing

Conformity Assessment Route:

IVDD 98/79/EC Annex III (Section 6)

We here with 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.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

POLISH CENTRE FOR TESTING AND CERTIFICATION**469 Pulawska Street, 02-844 Warsaw, Poland**

Certificate No: 1434-IVDD-448/2021

Validity of the Certificate: from 02.08.2021 to 27.05.2024

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 62366-1:2015	EN ISO 18113-4:2011
EN ISO 17511:2003	EN 13641:2002	EN 13532:2002	



Place, Date of Issue:

Shenzhen, Aug. 3rd, 2021

Position Held in Company

Management Representative

Signature:

