

# Declaration of Conformity

Certificate No.:EU2020006

**Manufacturer:**

Genrui Biotech Inc.  
4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.  
Tel: +86 755 26835560 Fax: +86 755 26678789

**European Representative:**

Wellkang Ltd.  
16 Castle St, Dover, CT16 1PW, UK

**Product Name:**

Novel Coronavirus (2019-nCoV) IgG/IgM Test Kit (Colloidal gold)

**Model:**

25T/kit, 50T/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 ISO13485:2016	EN ISO 23640:2015	EN ISO 14971:2012	EN ISO 18113-1:2011
EN ISO 15223-1:2016	EN 14136:2004	EN 13612:2002	EN ISO 18113-2:2011



Place, Date of Issue:

Shenzhen, Mar. 20<sup>th</sup>, 2020

Position Held in Company:

Management Representative

Signature:

