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:

New 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 13975:2003	EN 14136:2004	EN ISO 18113-2:2011
EN ISO 17511:2003			

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Standards Applied:

EN ISO 13485: 2016	Medical devices. Quality management systems. Requirements for regulatory purposes
EN ISO 15223-1: 2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 14971: 2012	Medical devices. Application of risk management to medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
EN 13957: 2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices. Statistical aspects
EN 14136: 2004	Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control material
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

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Place, Date of Issue: Shenzhen, Mar. 18th, 2020

Signature:

Name of Authorized Signatory: Ms. Yiping Li

Position Held in Company: Management Representative