CE Certification – Declaration of Conformity

CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT **Annex II and NOT self-test***)*

Manufacturer:	**New Gene (Hangzhou) Bioengineering Co., Ltd.**
Address:	Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China
EC Representative:	Wellkang Ltd 16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-Receptor Competitive Chromatography)
	Type/model, identification of product allowing traceability (Where applicable)	COVID-19-NG04
of Category	: **Common/Others IVD** (Devices of NOT **Annex II** and **NOT self-test**)	

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN 23640-2015	EN 13640:2002
	EN 980:2016	EN 13641:2002
	EN ISO 14971:2019	EN ISO 18113-1 2011
	EN 13612:2002	EN ISO 18113-4 2011
Conformity assessment procedure	**Module A (EC Declaration of Conformity) (Annex III, except point 6)**	
Notified Body (name & number)	**NOT applicable**	

Signed on: 7 May 2020. Place: Hangzhou City, Zhejiang Province, P. R. China

Signature (on behalf of the manufacturer): Mingfu Li

Name of authorized signatory: Mingfu Li
Position held in the company: General Manager
Company Seal/Stamp:

杭州)生物工程有限公司 3301081000835O