

CE Certification – Declaration of Conformity



EC Declaration of Conformity



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 Antigen Detection Kit (Colloidal Gold)
	Type/model, identification of product allowing traceability (Where applicable)	COVID-19-NG02
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:

