EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *Anhui Formaster Biosci Co.,Ltd.*
Address: *NO.1 Fumao Road, Wuwei Economic and DevelopmentZone, Wuhu Anhui,P.R China*

Product/s	*Model*
New Coronavirus(COVID-19) IgG/IgM Rapid Test Device	Device

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive(Model A)

Applicable Standards: *EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 18113-3:2011; EN ISO 23640:2015;EN 62366:2008.*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd,located at Suite B,29 Harley Street, London W1G 9QR,England,United Kingdom to act as our European Authorised Representative as defined in the aforementioned Directive.

ANHUI FORMASTER BIOSCI CO.,LTD 安徽福恩生物科技有限公司 3402250131745

Anhui,February 25th,2020
Place,date

Wang Jue General Manager
Legally binding signature ,Position