EC Declaration of Conformity

according to the Directive 98/79/EC

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

Manufacturer	Guangdong Wesail Biotech Co., Ltd. Room 403, Building 1, 1 Taoyuan RD, Songshan Lake Science and Technology Industrial Park, Songshan Lake, Dongguan, Guangdong, 523808, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Product/s	Coronavirus COVID-19 IgM/IgG Test Kit Model:1 test/kit, 20 tests/kit
Classification	Others/General
Conformity Assessment Route	Annex Ⅲ, except point 6, of Directive (Module A)

Applicable Standards			
	EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
	EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
	EN 13975:2003	EN ISO 17511:2003	EN ISO 14971:2012
	ISO 14971:2019	EN ISO 13485:2016	ISO 15198:2004

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.

Signed this Day/ 21st of Month/ September of Year/ 2020, Place (Dongguan), China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp: