CE 0123

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to IVDD annex III.6)

Manufacturer	Guangdong Wesail Biotech Co., Ltd. 2F, Building 1, 5 Hualian Street, Songshan Lake Science and Technology Industrial Park, Songshan Lake, 523808 Dongguan, Guangdong, China
European Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65•80339 Munich•Germany
Notified body ID	0123
Product/s	COVID-19 Ag Test Kit
Model:	1 test/kit(BE0081), 5 tests/kit(BE0082), 10 tests/kit(BE0083), 20 tests/kit(BE0080)
Classification	Self Testing
Conformity Assessment Route	IVDD annex III.6

Applicable Standards	EN ISO 18113-1:2011	EN ISO 18113-4:2011	EN 13612:2002	EN 13641:2002
	EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003	EN 13532:2002
	EN ISO 14971:2012	EN ISO 23640:2015	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/ 31st of Month/ May of Year/ 2021 , Place (Dongguan), China

EC Certificate No. : No. V9 108683 0002 Rev.00

Valid From: 2021-05-31

Valid until: 2024-05-26

Signature (on behalf of the manufacturer):

Name of authorized signatory: Dong Yu

Position held in the company: General Manager

Company Seal/Stamp: