



## 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:**

