



## EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

**Manufacturer:** Guangzhou Wondfo Biotech Co., Ltd.  
**Address:** No.8, Lizhishan Road, Science City, Luogang District,  
510663, Guangzhou, P.R. China

**EC Authorised Representative:** Qarad EC-REP BV  
**Address:** Pas 257, 2440 Geel, Belgium

### ***In Vitro* Diagnostic Medical Device(s):**

**Product Name:** Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)  
**Cat. No.:** W634P0024, W634P0025, W634P0026,  
W634P0027, W634P0028, W634P0029  
**IVDD Classification:** Non-Annex II, for self-testing

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

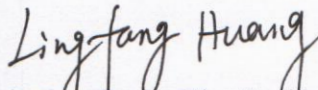
The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2019	EN ISO 18113-4:2011	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2016	EN 13532:2002
EN 62366-1:2015		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, including 6**

**Notified Body (if consulted):** TÜV SÜD Product Service GmbH (NB # 0123)  
**Address:** Ridlerstraße 65, 80339 München, Germany  
**EC Certificate(s):** No. V9 058008 0037 Rev. 00  
**Expiry date of the Certificate(s):** 2024-05-26

**Signature of manufacturer (Name and function):**

 2021.6.3  
Lingfang Huang, Vice-President of Regulatory Affairs

**Issue date:** 2021-06-03