Wondfo

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): Lingfang Huang 2021.6.3

Lingfang Huang, Vice President of Regulatory Affairs

Digitally signed by Turcanu Stefan
Date: 2021.11.24 11:22:11 EET
Reason: MoldSign Signature
Location: Moldova

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