# EC DECLARATION OF CONFORMITY

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

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| **Manufacturer:** | Guangzhou Wondfo Biotech Co., Ltd. | |
| **Address:** | No.8, Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China | |
| **In vitro diagnostic device(s):** | **Product Name:** | **Cat. No.:** |
| | Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) | W633P0001, W633P0002, W633P0003, W633P0004, W633P0005, W633P0006, W633P0007, W633P0008, |
| | **IVDD Classification:** | Other, for professional use |

This declaration of conformity is issued under the sole responsibility of the manufacturer that 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:

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| EN ISO 13485: 2016 | EN ISO 14971: 2012 | EN 13612:2002 |
| EN ISO 15223-1:2016 | EN ISO 18113-1: 2011 | EN ISO 18113-2: 2011 |
| EN ISO 23640: 2015 | EN 13641: 2002 | EN 62366-1: 2015 |
| EC 1272/2008 | | |

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**, excluding 6**

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| **Notified Body (if consulted):** | Not applicable. |

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

**Qarad BV**, Cipalstraat 3, 2440 Geel, Belgium

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| Guangzhou Feb. 2, 2021 | Yaqin Chi, Vice-President of Regulatory Affairs<br>Yaqin Chi |
| (Place and date of issue) | (name and signature or equivalent marking of authorized person) |