

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													
In vitro diagnostic device(s):	Product Name:	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)												
	Cat. No.:	W196, W196P0005, W196P0006, W196P0007, W196P0008, W196P0009, W196P0010, W196P0011, W196P0012												
	IVDD Classification:	Other, for professional use												
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 <i>in vitro</i> Diagnostic Medical Devices.														
The following (harmonized) standards have been applied:														
<table border="0"> <tr> <td>EN ISO 13485: 2016</td> <td>EN ISO 14971: 2012</td> <td>EN 13612:2002</td> </tr> <tr> <td>EN ISO 15223-1:2016</td> <td>EN ISO 18113-1: 2011</td> <td>EN ISO 18113-2: 2011</td> </tr> <tr> <td>EN ISO 23640: 2015</td> <td>EN 13641: 2002</td> <td>EN 62366:2008</td> </tr> <tr> <td>EC 1272/2008</td> <td></td> <td></td> </tr> </table>			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 62366:2008	EC 1272/2008		
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EN ISO 23640: 2015	EN 13641: 2002	EN 62366:2008												
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: <u>Annex III, excluding 6</u>														
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, Ciplastraat 3, 2440 Geel, Belgium														
<u>Guang Zhou, January 18, 2021</u>	Yaqin Chi, Vice-President of Regulatory Affairs <u>Yaqin Chi</u>													
(Place and date of issue)	(name and signature or equivalent marking of authorized person)													