EC DECLARATION OF CONFORMITY

According 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:**	**Cat. No.:**
	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	W196
	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:

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

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**

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

Guangzhou Nov. 6, 2020	Yaqin Chi, Regulatory Affairs Director Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)