

DECLARATION OF NOTIFICATION

Date: November 6, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BV hereby declares that:

Guangzhou Wondfo Biotech Co. Ltd.
No. 8 Lizhishan Road, Science City Luogang District,
Guangzhou 510663
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD product (for professional use only):

Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) (REF: W196)

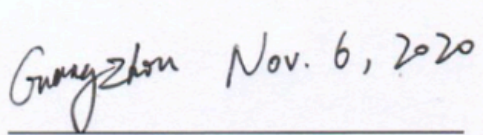
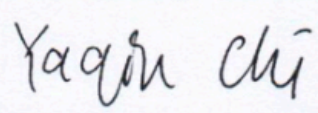
The notification to the Belgian Competent Authorities has been carried out on August 11, 2020 by Qarad BV, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd. On November 6th, a notification of change was carried out during which the new product name Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) was notified.

Sara Van Wouwe
Device Compliance Assistant
Qarad BV
Authorized Representative



Digitally signed by Sara
Van Wouwe (Signature)
Date: 2020.11.06
15:33:05 +01'00'

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: <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			
 _____		Yaqin Chi, Regulatory Affairs Director  _____	
(Place and date of issue)		(name and signature or equivalent marking of authorized person)	

