qarad
European Regulatory Services

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: 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)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 058008 0025 Rev. 01

Holder of Certificate: **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1914118

Valid from: 2020-02-10
Valid until: 2021-01-31

Date, 2020-02-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17