Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATION

To Whom This May Concern:

This is to certify that the **Wondfo 2019-nCoV Antigen Test (Lateral flow) (Specimen: Nasopharyngeal or Oropharyngeal swabs)** Mfd by: Guangzhou Wondfo Biotech Co., Ltd. – No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China (Specimen: Nasopharyngeal or Oropharyngeal swabs) has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has Medical device registration certificate from National Medical Products Administration (NMPA) of China. With this approval, the company is required to indicate in the product label or in the accompanying product insert the following statement:

"This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required"

The result of performance evaluation conducted by the Foundation for Innovative Diagnostics (WHO-FIND) as recommended by the Research Institute for Tropical Medicine (RITM) is CT < 30 (92.2%) diagnostic sensitivity and 100% diagnostic specificity. The product complied with the required specificity >80% and sensitivity >97%, based on the FDA Memorandum 2021-009.

This certification is issued upon the request of [redacted] **INC** with business address at 3rd Floor, ALP Tower, 609 Tres De Abril Street, Labangon, Cebu City for whatever legal purpose this may serve.

This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

This certificate shall be valid for one year and shall expired on July 23, 2022.

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATIENZO
Director IV
Center for Device Regulation, Radiation Health, and Research

Not valid without FDA Seal

Ref No. : 5202021114507630
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