Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20213196

23 NOV 2021

TO: **ALL CONCERNED CONCERNED STAKEHOLDERS AND GENERAL PUBLIC**

SUBJECT: **Delisted Companies with issued FDA - Special Certification for COVID-19 Test Kits**

The Food and Drug Administration (FDA) informs all concerned stakeholders and the general public that the following companies have failed to comply and submit documents, as required by the FDA Memorandum No. 2020-011. Thus, the Special Certification for COVID-19 Test Kits issued to the following companies are automatically revoke and cancel:

	Company's Name	Product Name	SC Control Number	Classification
1	MDRX ENTERPRISE	SARS-CoV-2 ANTIBODY TEST (LATERAL FLOW METHOD) manufactured by Guangzhou Wondfo Biotech Co., Ltd.	SC-COVID19-2020-123	ANTIBODY
2	INTELMED LABORATORIES MANUFACTURING INC	2019-nCoV ANTIBODY TEST (COLLOIDAL GOLD) manufactured by Innovita (Tangshan) Biological Technology Co., Ltd	SC-COVID19-2020-033	ANTIBODY

For more information and inquiries. Kindly contact the FDA – Center for Device Regulation, Radiation Health, and Research through e-mail address at **cdrrhr@fda.gov.ph** or call **(02) 8857-1900** loc. **8301**.

Dissemination of this advisory to all concerned is hereby requested.

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