Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 DEC 2021

FDA ADVISORY
No. 2021-2452-A

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Lifting the Advisory of NADAL COVID-19 Ag Test under FDA Advisory No. 2021-2452 entitled: Caution on the purchase and use of certain COVID-19 Test Kits following the performance validation conducted by the RITM**

The Food and Drug Administration (FDA) informs all healthcare professionals and general public that the advisory on **NADAL COVID-19 Ag Test** manufactured by Nal Von Minden GmbH under FDA Advisory No. 2021-2452 dated 08 October 2021 is hereby lifted pursuant to the compliance of the market authorization holder to existing and applicable laws, rules, and regulations.

The FDA issued Special Certification for the above-mentioned product with certificate number SC-2021-094 under company Diagnostika Pilipinas, Inc.

The provisions of FDA Advisory No. 2021-2452 providing lists of companies with issued Special Certificate and failed performance validation conducted by the RITM is still in effect.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to existing laws, rules, and regulations.

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

To report any sale or distribution of unregistered medical device products, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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