Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 MAR 2023

FDA ADVISORY
No. 2022-0064-A

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

SUBJECT: **LIFTING OF THE FDA ADVISORIES ISSUED TO CLUNGENE RAPID TEST COVID-19 ANTIGEN RAPID TEST CASSETTE**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, Clungene Rapid Test COVID-19 Antigen Rapid Test Cassette, has been issued with FDA Special Certificate to the Market Authorization Holder (MAH), Sparti Logistics Corporation, in accordance with existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2022-0064, FDA Advisory No. 2021-3523 and FDA Advisory No. 2021-3195 dated 23 November 2021, 14 December 2021 and 25 January 2022 are hereby lifted.

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 unnotified medical device, contact the online reporting facility, **eReport**, through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

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