



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



14 JUN 2023

FDA ADVISORY

No. 2023-0669-A

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Lifting of the FDA Advisory No. 2023-0669 entitled Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product “ Promisemed Blood Lancet ”

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, Unregistered Promisemed Blood Lancet, has been issued an FDA Certificate of Medical Device Registration to the Market Authorization Holder (MAH), Meditest Marketing Solution Corp., in accordance to existing FDA rules and regulations.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2023-0669 dated 12 April 2023 is hereby lifted.

The public health warning imposed on the remaining product listed in FDA Advisory No. 2023-0669 shall remain to be upheld and shall not be affected by the issuance of this advisory. Furthermore, 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 the 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 cdrhr@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.


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Director General

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