Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2022-1765-A

13 OCT 2023

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

SUBJECT: **Lifting of the FDA Advisory No. 2022-1765 entitled "Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Product TOP CARE AUTOMATIC LANCING DEVICE"**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, Unregistered Top Care Automatic Lancing Device, has been issued a proper authorization in the form of a Certificate of Medical Device Notification to the Market Authorization Holder (MAH), Intramed Healthcare Products Inc., 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. 2022-1765 dated 24 October 2022 is 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 an 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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