Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2363-A

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

SUBJECT: **Lifting the Advisory of Alpk2 Aneroid Sphygmomanometer under FDA Advisory No. 2021-2363 entitled Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product ANEROID SPHYGMOMANOMETERS**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product **Alpk2 Aneroid Sphygmomanometer** has been issued a FDA Certificate of Exemption to the Market Authorization Holder (MAH), Medical Center Trading Corporation, with LRD/CDRRHR_EXEMP-2019-15745 in accordance to FDA rules and regulations. Based on FDA Circular No. 2020-001, all CoE for Class A medical devices issued from 25 February 2014 shall remain valid until 03 November 2021.

Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2021-2363 dated 24 September 2021 is hereby lifted.

The public health warning imposed on the remaining products listed in FDA Advisory No. 2021-2363 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 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 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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