

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2020-178-A 2 7 MAR 2020

TO:

ALL **HEALTHCARE** PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Lifting the Advisory of the Registered Medical Device under FDA Advisory No. 2020-178, Subject "Public Health Warning

Against the Purchase and Use of the Unregistered Medical

Device Alaris® Secondary Syringe Adapter"

The Food and Drug Administration (FDA) informs all healthcare professionals and the public that the medical device product "Alaris® Secondary Syringe Adapter" has been registered by the Market Authorization Holder (MAH), KSM Healthcare Inc., with FDA registration number MDR-04674 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. 2020-178 is hereby lifted.

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.

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.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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