Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-309-A

20 MAR 2020

TO: **THE GENERAL PUBLIC**

SUBJECT: **Lifting the Advisory of the Registered Medical Device Product "Air Life Gauze Bandage 4" x 10 yds, 40's/40's 19 x 10 mesh under FDA Advisory No. 2018 – 309 "Public Health Warning Against the Purchase and Use of Medical Device with Expired Certificate of Product Registration (CPR) "**

The Food and Drug Administration (FDA) informs the public that the medical device product **Air Life Gauze Bandage 4" x 10 yds, 40's/40's 19 x 10 mesh** with **CPR No. MDR-08861**, has been registered by the Market Authorization Holder (MAH), Airlife International Trading Corporation, 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. 2018-309 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

DTN: 20200127012148