Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA ADVISORY**
No. 2019-333-A

01 SEP 2022

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

**SUBJECT:** **Lifting of the FDA Advisory No. 2019-333 entitled "Public Health Warning Against the Purchase and Use of the Unregistered Medical Device "I-SHIELD GAUZE BANDAGE 3" X 10 YARDS"**

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The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the medical device product, i-shield Gauze Bandage 3" x 10 yards has been issued an FDA Certificate of Medical Device Registration to the Market Authorization Holder (MAH) in accordance to existing FDA rules and regulations.


Figure 1. i-shield Gauze Bandage 3" x 10yards

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Accordingly, the warning against the purchase and use of the product as mentioned in FDA Advisory No. 2019-333 dated 08 October 2019 for the above-mentioned product 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 unregistered medical device, contact the online reporting facility, **eReport**, through e-mail at **ereport@fda.gov.ph**.

**DR. SAMUEL A. ZACATE**
Director General

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