

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





FDA ADVISORY No. 2022 - 1586 - Δ

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Lifting of the FDA Advisory No. 2022-1586 entitled "Public Health Warning Against the Purchase and Use of the

**Following Unnotified Medical Device Products:** 

1. MED GUARD COTTON BALLS

2. MED GUARD PURE AND ABSORBENTCOTTON"

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that Outshine Philippines Inc., the distributor of Med Guard Cotton Balls and Med Guard Pure and Absorbent Cotton had complied with the FDA rules and regulations. The said establishment removed the claims that these products are intended for medical use.

Accordingly, the warning against the purchase and use of the abovementioned products as mentioned in FDA Advisory No. 2022-1586 dated 06 September 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 <a href="mailto:cdrrhr@fda.gov.ph">cdrrhr@fda.gov.ph</a> or call (02) 8857-1900 loc. 8301.

To report any sale or distribution of 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.

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