

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2018 - 158 0 3 MAY 2018

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Lifting the Advisory of CARDINAL CARE PREMIUM DISPOSABLE SYRINGES WITH MOUNTED NEEDLE under FDA Advisory No. 2018-068, subject "Public Health Warning Against the Purchase and Use of the Unregistered

Medical Device Products"

The Food and Drug Administration (FDA) informs the public that the advisory on the medical device product "Cardinal Care Premium Disposable Syringes with Mounted Needle" under FDA Advisory No. 2018-068 dated 07 March 2018 is hereby lifted pursuant to the compliance of the market authorization holder to existing and applicable laws, rules, and regulations.



Figure 1. Cardinal Care Premium Disposable Syringes with Mounted Needle





FDA approved on the stickering of the correct registration no. (DVR-7937) on the blister pouch of the 9,544 pcs. recalled Cardinal Care Premium Disposable Syringes with Mounted Needle with Lot no. 170725 expiring on 24 July 2022.

The provisions of FDA Advisory No. 2018-068 indicating unregistered medical device products are still in effect.

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, please e-mail us at info@fda.gov.ph or call the Center for Device Regulation, Radiation Health, and Research at (02) 857-1900 local 8301. To report sale or distribution of any unregistered medical device products, kindly email us via report@fda.gov.ph.

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Director General

