Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

127 MAR 2018

FDA ADVISORY
No. 2018-114

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

SUBJECT: **VOLUNTARY RECALL OF CADD® MEDICATION CASSETTE RESERVOIR, PART NUMBER 21-7001-24, 21-7002-24 AND 21-7100-24**

The Food and Drug Administration (FDA) informs the public and all healthcare concerned professionals that Smiths Medical manufacturer of above mentioned product with Delex Pharma International Inc. as their distributor has voluntarily recalled certain lots of 50 and 100ml Non Flow-Stop CADD® Medication Cassette Reservoirs, part numbers 21-7001-24, 21-7002-24 and 21-7100-24.

Part number 21-7002-24

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph

Smiths Medical informed the FDA that certain Non Flow-Stop CADD® Medication Cassette Reservoirs, may have been manufactured with an incorrect pressure plate. When the cassette is attached to the pump, the tubing could be restricted, such that it is partially or completely occluded. The occlusion could pose risk to the patient of no delivery

Risk to health:

> *The immediate impact to the patient depends on the patient condition, the therapy involved, and possibly the time to discover problem. Potential health consequence due to no delivery may result in immediate or delayed effects. The severity of adverse effects, as well as the risk of long term consequences, can depend on the specific medication and the patient's current or existing condition.*
>
> *The risk may occur when the Clinician is not aware of the issue because the pump will continue to operate as if it is infusing medication without alarming for an occlusion.*

Distributors, retailers, hospitals and all healthcare professionals / users are advised to discontinue further distribution, sale and use of the said affected medical device product, and coordinate with Delex Pharma International Inc.

For more information and inquiries, please e-mail us at cdrrhr_prsdd@fda.gov.ph. or call us at the Center for Device Regulation, Radiation Health and Research (CDRRHR) hotline (02) 857-1900 local 8301.

NELA CHARADE G. PUNO, RPh
Director General

20180126102911