Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

23 MAR 2018

FDA ADVISORY
No. 2018-101

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

SUBJECT: **VOLUNTARY RECALL OF MEDFUSION® SYRINGE PUMP MODELS, SERIES 3500 AND 4000**

The Food and Drug Administration (FDA) informs the public and all concerned healthcare professionals that Smiths Medical has voluntarily recalled certain Medfusion® Syringe Pump Models, Series 3500 and 4000, which were manufactured or serviced between February 2015 and November 2017, with the following product codes:

Medfusion 3500 Series Syringe Pump

Medfusion 4000 Series Syringe Pump

Model 3500 Product Codes
3500-0600-00
3500-0600-01
3500-0600-50
3500-0600-51
3500-0600-82
3500-306
3500-415
3500-500

Model 4000 Product Codes
4000-0101-50
4000-0101-51
4000-0105-50
4000-0105-51
4000-0106-00
4000-0106-01

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Smiths Medical informed the FDA that certain Medfusion® Syringe Pump Model Series 3500 and 4000, which were manufactured or serviced between February 2015 and November 2017, may not be recognizing or may be misidentifying loaded medication syringes. The inability of a pump to recognize a syringe (i.e. the size of the syringe is unknown to the pump) result in an inability to complete pump programming. Misidentification of a syringe may also occur, in which the pump misinterprets the syringe size.

Risk to health:

> *The inability of the pump to recognize a syringe can potentially lead to a delay in the initiation of an infusion, due to clinicians being unable to complete programming. Interruption of therapy may also potentially occur if loss of recognition occurs during an active infusion (Note: the pump will alarm in this scenario).*
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> *Misidentification of syringe size may potentially result in over-delivery or under-delivery if the clinician does not notice the pump's misidentification of the syringe prior to starting an infusion.*

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

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.

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Director General

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