



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



28 JUN 2018

FDA ADVISORY
No. **2018-213**

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

**SUBJECT: VOLUNTARY RECALL OF STAY SAFE DISINFECTION
CAP WITH BATCH NUMBER Z1Z04300**

The Food and Drug Administration (FDA) informs the public and all concerned healthcare professionals that Fresenius Medical Care Philippines, Inc. has voluntarily recalled the Stay Safe Disinfection Cap with batch number Z1Z04300.



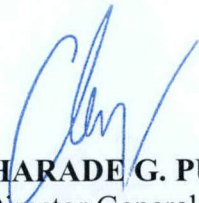
It has been discovered that this batch number was distributed without local label sticker. The application stickers for the mentioned batch was missed by their sub-distributor. Appropriate corrective and preventive actions will be instituted to prevent recurrence.



As a mitigating measure they will provide replacement of the said medical device product to the affected customers to ensure continuity of care.

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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