

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



04 November 2013

FDA Advisory No. 2013-048

SUBJECT: QUALITY HOLD ON SOLUSETTM 100 BURETTE IV

(INTRAVENOUS) SET IMPORTED BY HOSPIRA PHILIPPINES,

INC.

In the interest of public health and safety, the Food and Drug Administration (FDA) and Hospira Philippines, Inc. will jointly undertake a quality hold of the product **SolusetTM 100 Burette IV (Intravenous) Set**, with its clamp and secure lock. Hospira Philippines, Inc., as part of their due diligence responsibility, will do a quality check on SolusetTM 100 Burette IV (Intravenous) Set found in the market, specifically those with Batch Numbers 1707456 and 1707856.

Soluset[™] 100 Burette IV (Intravenous) Set is manufactured by Hospira de Costa Rica Ltd., Costa Rica and registered in the Philippines with FDA Registration No. DVR-2362.

All consumers and health professionals are advised not to use the said batches of SolusetTM 100 Burette IV (Intravenous) Set until such time that the FDA and Hospira Philippines, Inc. shall have issued an advisory that the quality hold has been lifted. Likewise, distributors and drug outlets are ordered to remove the stocks from their shelves and hold the said stocks until the FDA and Hospira Philippines, Inc. shall have conducted the quality check. For any inquiries, email us at info@fda.gov.ph.

For strict compliance of all concerned.

KENNETH Y HARTIGAN-GO, MD
Acting Director General



