Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

09 June 2014

FDA Advisory
No. 2014-046

SUBJECT : **LIFTING OF THE QUALITY HOLD ON SOLUSET™ 100 BURETTE INTRAVENOUS (IV) SET IMPORTED BY HOSPIRA PHILIPPINES, INC.**

On 04 November 2013, FDA Advisory No. 2013-048: Quality Hold on Soluset™ 100 Burette IV (Intravenous) Set imported by Hospira Philippines, Inc. was issued to conduct quality check.

Testing was conducted by the Laboratory Unit of the Food and Drug Administration on 09 December 2014 on 18 sets of Soluset™ Burette Intravenous (IV) Set batch number 170785G. The test has a satisfactory result and passed the sterility test.

A separate investigation was conducted by Hospira Philippines, Inc, on all the remaining stocks of Soluset TM Burette Intravenous (IV) Set. Historical complaint search, review of the batch record, evaluation of the inspection results of visual checking and physical evaluation of the two lot numbers involves were conducted by the company. This resulted to no discrepancies that may have contributed to the complaint. The probable causes that were concluded by the company that might have attributed to the complaint are improper use of hairnet and gowning during the coiling, packaging or sealing process. The QA/Production management personnel of Hospital were notified. Proper gowning and wearing of hairnet was implemented in the clean room to mitigate this kind of problem from occurring.

In this regard, the quality hold on Soluset TM Burette Intravenous (IV) Set imported by Hospira Philippines, Inc. with Batch Numbers 170145G and 170785G is hereby lifted effective immediately. Hospira Philippines, Inc, can now sell the products.

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