Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2018-157

03 MAY 2018

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

SUBJECT: **LIFTING THE ADVISORY OF SURE-GUARD PREGNANCY TEST KIT UNDER FDA ADVISORY NO. 2018-130, SUBJECT "PUBLIC HEALTH WARNING AGAINST THE PURCHASE AND USE OF THE UNREGISTERED MEDICAL DEVICE PRODUCT SURE-GUARD PREGNANCY TEST KIT"**

The Food and Drug Administration (FDA) informs the public that the advisory on the medical device product "Sure-Guard Pregnancy Test Kit" under FDA Advisory No. 2018-130 dated 06 April 2018 is hereby lifted pursuant to the compliance of the market authorization holder to existing and applicable laws, rules, and regulations.

The medical device product is REGISTERED with Certificate of Product Registration No. IVDR-00229 under company AMB HK Enterprises, Inc.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to existing laws, rules, and regulations.

For more information and inquiries, please e-mail us at info@fda.gov.ph or call the Center for Device Regulation, Radiation Health, and Research at (02) 857-1900 local 8301. To report sale or distribution of any unregistered medical device products, kindly email us via report@fda.gov.ph.

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Director General

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