Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 SEP 2021

FDA ADVISORY
No. 20212365

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product FIRST AID DISPOSABLE VINYL GLOVES 100PCS (CLEAR WHITE)**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unnotified medical device product:

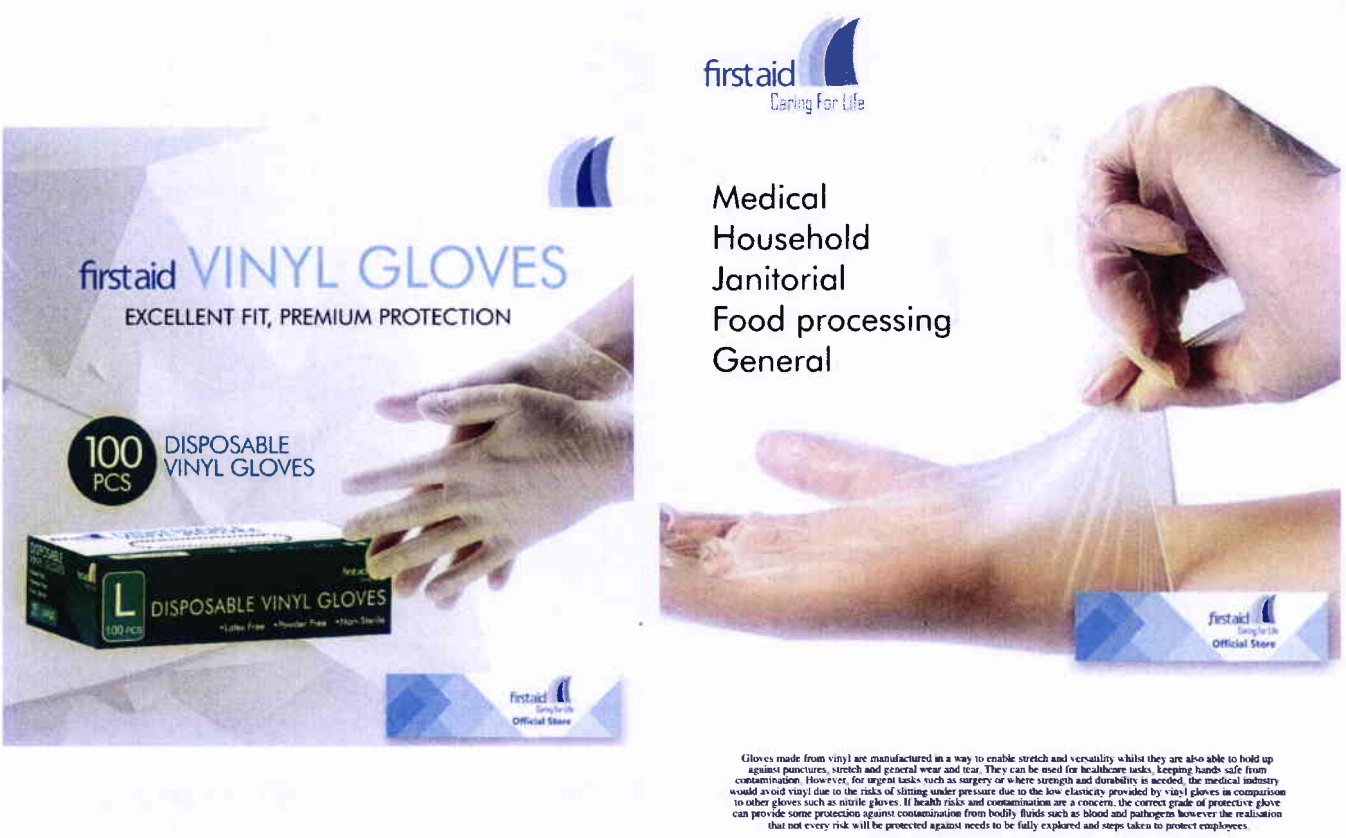

Figure 1. Unnotified First Aid Disposable Vinyl Gloves 100pcs (Clear White)

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TÜVRheinland CERTIFIED
Management System ISO 9001:2015
www.tuv.com ID 9105073396

The FDA verified through post-marketing surveillance that the above mentioned medical device product is not notified and no corresponding Product Notification Certificate has been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this unnotified medical device product has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

Additionally, with the issuance of FDA Circular No. 2020-010 entitled "Prohibition of Online Selling of Unregistered/Unnotified Medical Devices," the FDA prohibits the online selling of medical devices and supplies without their corresponding authorizations.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Notification Certificate is issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been notified with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Notification number on the product label in the form of DVR-xxx, MDR-xxx, or CMDN-xxx.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unnotified product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr@fda.gov.ph** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unnotified medical device, contact the the online reporting facility **eReport** through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

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Director General

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