



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No: **2021-3301**

01 DEC 2021

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

**SUBJECT: Public Health Warning Against the Purchase and Use of the Banned Medical Device Product SOLITAIRE SURGICAL GLOVES (RUBBER LATEX, PRE-POWDERED SIZE 7.5)**

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



Figure 1. Banned Solitaire Surgical Gloves (Rubber Latex, Pre-Powdered size 7.5)

The FDA verified through post-marketing surveillance that the above mentioned product is a banned medical device. Pursuant to FDA Advisory No. 2017-180 and FDA Memorandum 2017-016, effective 01 January 2019, the importation, distribution, manufacture, storage, distribution, and use of: 1. Powdered Surgeon's Gloves; 2. Powdered Patient Examination Gloves; and 3. Absorbable Powder for Lubricating a Surgeon's Glove are prohibited and are considered as a direct violation to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009."

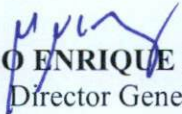
All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this banned medical device product.

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at [cdrrhr@fda.gov.ph](mailto: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 banned medical devices, contact the online reporting facility **eReport** through e-mail at [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph).

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

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