Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2023-1892

29 AUG 2023

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Banned Medical Device "MAXWELL POWDERED SMOOTH SURFACE LATEX EXAMINATION GLOVES"**

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

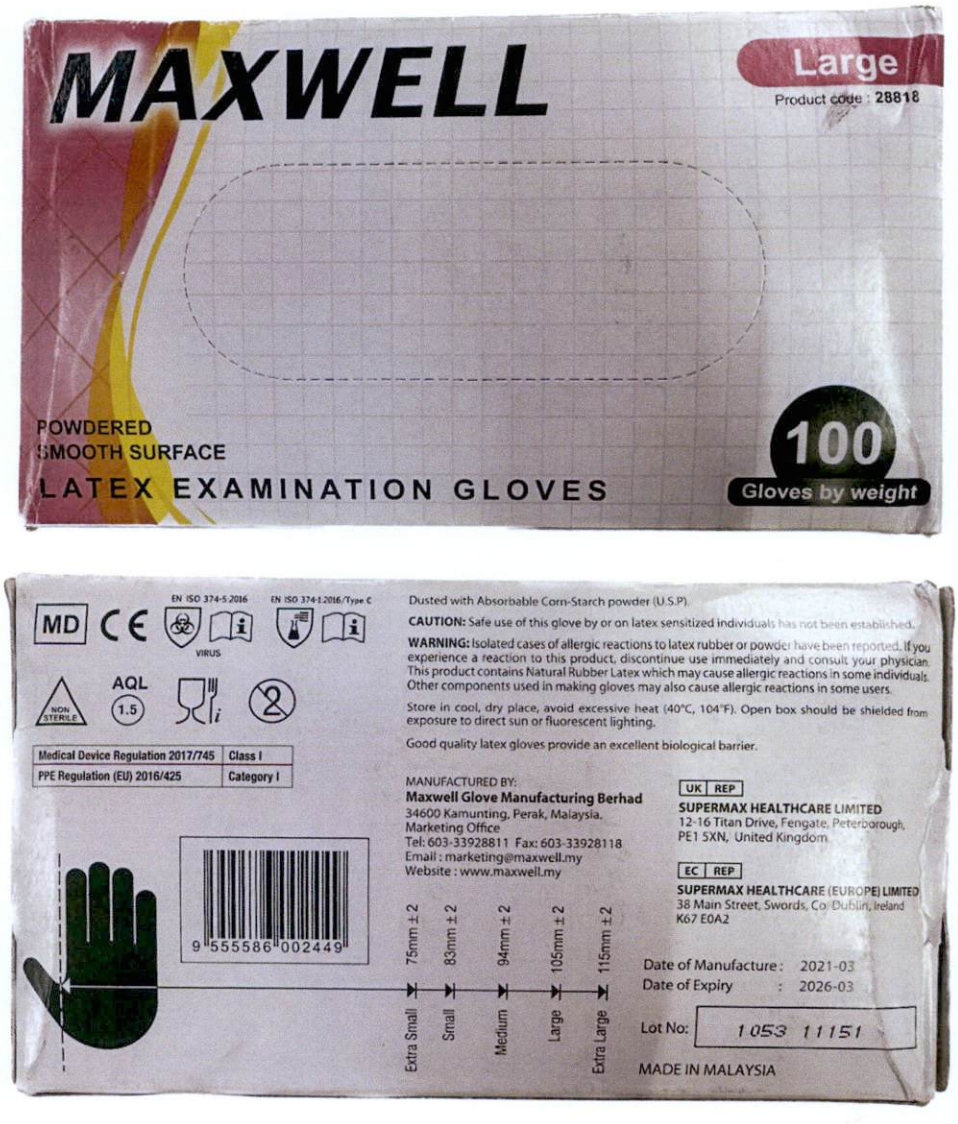

Figure 1. Banned Maxwell Powdered Smooth Surface Latex Examination Gloves

The FDA verified through post-marketing surveillance that the above-mentioned medical device product is a banned medical device. Pursuant to FDA Advisory No. 2017-180 and FDA Memorandum No. 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 lubrication a surgeon's gloves are prohibited and considered as a direct violation to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009".

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product.

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** indicating on the subject the concerned Advisory, or call **(02) 8857-1900 loc. 8301.**

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

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

DTN: 20230706092424