

FDA ADVISORY
No. **2024-0658**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Medical Device Product "SURESHOT DISPOSABLE SYRINGE" with Expired Certificate of Product Registration (CPR)

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the medical device product with expired Certificate of Product Registration (CPR):

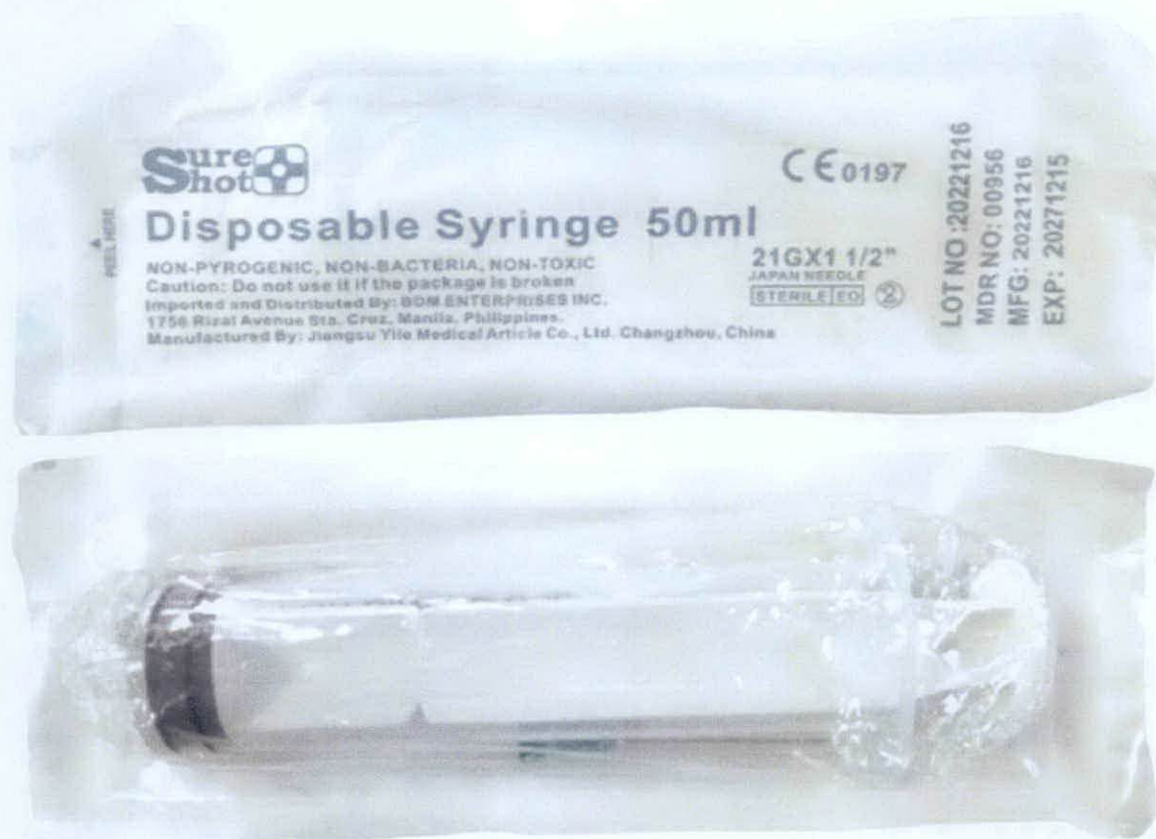


Figure 1. SureShot Disposable Syringe with Expired CPR

The FDA verified through post-marketing surveillance that the above-mentioned medical device product has an expired CPR. 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.



All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until the Product Registration Certificate is renewed, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered 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 Registration number on the product label in the form of either CMDR-xxx, DVR-xxx, or MDR-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 the abovementioned 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 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 20231020181605 / 20231020182512