



11 9 JUL 2023

**FDA ADVISORY**  
No: **2023-1708**

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

**SUBJECT: Public Health Warning Against the Purchase and Use of the Unnotified Medical Device Product “BT21 PLASTER”**

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

**BT21 CUTE BAND AID SET**  
5.0 ★★★★★ 8 Ratings 24 Sold

**₱79 - ₱99**

Shipping: Shipping Discount (Shipping discount for orders over ₱249)  
Shipping To: Binondo, Metro Manila  
Shipping Fee: ₱0 - ₱38

Color: Blue Box Yellow Box Pink Pack Green Pack  
Size: BT21  
Quantity: 1 (12 pieces available)

Share: [Social Media Icons] Favorite (35) [Shopee Guarantee]

Figure 1. Unnotified BT21 Plaster Advertised at Shopee.ph

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 product 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.

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](http://www.fda.gov.ph). You may also look for the FDA Notification number on the product label in the form of either CMDR-xxx, MDR-xxx, DVR-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](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 unnotified medical device, 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.



DR. SAMUEL A. ZACATE  
Director General *mf*

DTN 20230417143655