



FDA ADVISORY
No. **2024-0031**

15 JAN 2024

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Following Unnotified Medical Device Products:

- 1. “ADHESIVE WOUND DRESSING – ADHESIVE ISLAND DRESSING WITH NON-ADHERING PAD”**
- 2. “5M WATERPROOF MEDICAL TAPE ANTI-ALLERGIC PU FILM GAUZE PAD TRANSPARENT FIXATION TAPE HEALTH CARE”**

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

The screenshot shows a Shopee product page for '50PCS Breathable Non-woven Large Adhesive Wound Dressing big First Aid Bandage Pad Plasters 6*7cm'. The product is advertised with a price of P54, marked as 47% off from P102. It has a 4.9 star rating and 1.2K ratings. The product image shows a package of 'ADHESIVE WOUND DRESSING' with a CE mark and FDA logo. The listing includes various shipping options and a 'Buy Now' button.

Figure 1. Unnotified Adhesive Wound Dressing – Adhesive Island Dressing with Non-Adhering Pad advertised at Shopee.com



The screenshot displays the Shopee.com interface for a medical tape product. The top navigation bar includes links for Seller Centre, Start Selling, Download, and social media. The main header features the Shopee logo, a search bar with a promotional message, and a shopping cart icon. The breadcrumb trail indicates the product's location: Health & Personal Care > Medical Supplies > First Aid Supplies > 5M Waterproof Medical Tape Anti-allergic PU Film Gauze Pad Transparent Fixation Tape Health Care.

The product listing includes a detailed image of the tape with a grid pattern and a list of design highlights:

- Can Be Cut
- Not Allergic
- Waterproof
- Medical Adhesive
- Imported Glue

Key product details shown are:

- Product Name:** 5M Waterproof Medical Tape Anti-allergic PU Film Gauze Pad Transparent Fixation Tape Health Care
- Rating:** 4.8 stars (273 ratings)
- Sales:** 1.6K Sold
- Price:** ₱259 - ₱899 (original) / ₱39 - ₱125 (current, 85% OFF)
- Shipping:** Shipping Discount, Shipping To Metro Manila, Shipping Fee ₱0 - ₱38
- Size Options:** 5cmx5m, 10cmx5m, 15cmx5m
- Quantity:** 1 (4940 pieces available)

Figure 2. Unnotified 5M Waterproof Medical Tape Anti-allergic PU Film Gauze Pad Transparent Fixation Tape Health Care advertised at Shopee.com

The FDA verified through post-marketing surveillance that the abovementioned medical device products are not notified, and no corresponding Product Notification Certificates have 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 these unnotified medical device products have 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 products until the Product Notification Certificates are 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 either CMDN-xxx, DVR-xxx, or MDR-xxx.

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

The Bureau of Customs is urged to restrain the entry of these unnotified products.

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 devices, 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

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