

FDA ADVISORY
No. **20240661**

22 APR 2024

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. **“COMMODO WHEELCHAIR BLACK”**
2. **“COMMODO WITH FOAM”**

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



EightMed
YOUR MEDICAL SUPPLY PARTNER

**EIGHTMED
COMMODO
WHEELCHAIR
BLACK**
RST-OE-26

Order now !!

- **FEATURES**
 1. stainless steel body
 2. Solid Steel 3 pro long base
 3. adjustable height
 4. Flexible Gooseneck
 5. arms allows 360 degree adjustment
- **AVAILABLE**
 1. BLACK (PAINTED)
 2. CHROME



Figure 1. Unnotified Eightmed Commode Wheelchair Black (RST-OE-26) advertised at Facebook.com





EightMed
YOUR MEDICAL SUPPLY PARTNER

Order now !!

EIGHTMED
COMMUNE WITH FOAM
RST-OE-22

• **FEATURES**

- Adjustable height in easy to use push buttons
- 4 rubber tips to prevent slipping
- include plastic bowl with cover
- Armrest to provide support for the user
- foldable so you can stow it away when no longer use
- made of chrome plated steel
- can support weights up to 200 pounds



Figure 2. Unnotified Eightmed Commode with Foam (RST-OE-22) advertised at Facebook.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 CMDN-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 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.


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Director General

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