



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



FDA ADVISORY  
No. 2023-0158

27 JAN 2023

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

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

1. “A2-DX (FOR PREVENTING INVERSION/EVERSION WITH ANTERIOR STABILITY)”
2. “BODYMATE ELBOW (LIGHT COMPRESSION AND PROTECTION)”
3. “BODYMATE ELBOW (LIGHT COMPRESSION AND PROTECTION)”
4. “FILMISTA ANKLE (LIGHT COMPRESSION & PROTECTION OF THE ANKLE)”
5. “ZK-1 (SLEEVE-TYPE KNEE SUPPORT WITH PROTECTION PAD)”
6. “A1 (FOR PREVENTING INVERSION)”
7. “ZK-7 (FOR SPRAINS OF THE ACL, MCL, & LCL)”
8. “RK-2 (FOR TROUBLES AROUND PATELLA CAUSED BY RUNNING)”
9. “FINGER WRAP DOUBLE (SUPPORT FOR SPRAINED FINGERS)”
10. “FINGER WRAP SINGLE (FOR SPRAINED FINGER)”
11. “ARM SLEEVES (COMPRESSION AND SUPPORT)”
12. “BODYMATE KNEE (LIGHT COMPRESSION AND PROTECTION)”
13. “EK-3 (COMPRESSION AND PROTECTION)”
14. “ZW-5 (MODERATE BACK SUPPORT WITH 3D BACK PANEL)”
15. “THUMB GUARD (WITH CUSTOM FIT)”
16. “IW-2 SET (FOR SHOULDER AND BACK)”
17. “FOOTCRAFT AGILITY GRIP (FUNCTIONAL INSOLES)”
18. “FILMISTA THIGH (NEW GENERATION ULTRATHIN THIGH SUPPORT)”
19. “JK-2 (ADVANCED MODERATE SUPPORT FOR PATELLAR TENDON AND PATELLA)”
20. “JK-1 (PATELLAR TENDON AND PATELLA SUPPORT)”
21. “FOOTCRAFT STANDARD (FUNCTIONAL INSOLES)”



22. “BODYMATE WRIST (LIGHT COMPRESSION AND PROTECTION)”
23. “FOOTCRAFT CUSHIONED FOR SPIKE (FUNCTIONAL INSOLES)”
24. “THUMB GUARD SOFT”
25. “EK-5 (LATERAL / MEDIAL STABILIZATION)”
26. “SHOUDER WRAP (LIGHT COMPRESSION AND PROTECTION)”
27. “BODYMATE CALF (LIGHT COMPRESSION AND PROTECTION)”
28. “CALF AND ANKLE SLEEVES (COMPRESSION AND PROTECTION)”
29. “FILMISTA CALF (NEW GENERATION ULTRATHIN CALF SUPPORT)”
30. “FILMISTA WRIST (NEW GENERATION ULTRATHIN WRIST SUPPORT)”
31. “ELBOW BAND (FOR ELBOW TROUBLE WITH GOLF AND TENNIS)”
32. “RK-1 (FOR ILIOTIBIAL BAND SYNDROME)”
33. “BODYMATE ANKLE (LIGHT COMPRESSION AND PROTECTION)”
34. “AT-1 (FOR ACHILLES TENDON)”
35. “ZW-7 (STRONG AND FIRM BACK SUPPORT WITH 3D BACK PANEL)”
36. “ELBOW SLEEVE (SLEEVE-STYLE ELBOW SUPPORT)”
37. “FOOTCRAFT CUSHIONED FOR SPORTS (FUNCTIONAL INSOLES)”
38. “ZK-3 (FOR SPRAINS OF THE LCL AND MCL)”
39. “IW-1 SET (ICING SYSTEM WITH 1 ICE BAG)”
40. “CALF SLEEVES (COMPRESSION AND SUPPORT)”

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



Figure 1. Unnotified ZAMST A2-DX (For preventing inversion/eversion with anterior stability)

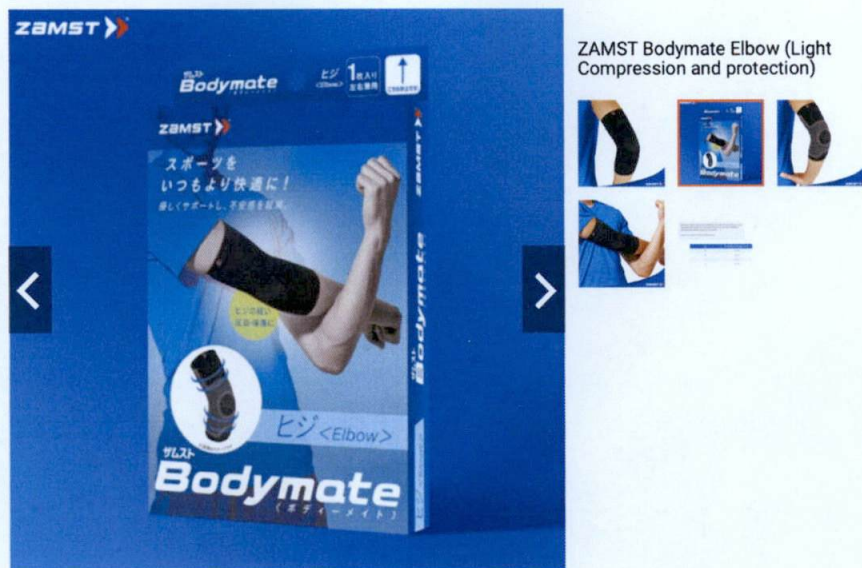


Figure 2. Unnotified ZAMST Bodymate Elbow (Light Compression and protection)



Figure 3. Unnotified ZAMST Bodymate Elbow (Light Compression and protection)



Figure 4. Unnotified ZAMST Filmista Ankle (Light Compression & Protection of the Ankle)



ZAMST ZK-1 (Sleeve-type knee support with protection pad)



Figure 5. Unnotified ZAMST ZK-1 (Sleeve-type knee support with protection pad)



ZAMST A1 (for preventing inversion)



Figure 6. Unnotified ZAMST A1 (for preventing inversion)



ZAMST ZK-7 (for sprains of the ACL, MCL, & LCL)



Figure 7. Unnotified ZAMST ZK-7 (for sprains of the ACL, MCL, & LCL)



Figure 8. Unnotified ZAMST RK-2 (for troubles around patella caused by running)



Figure 9. Unnotified ZAMST Finger Wrap Double (Support for sprained fingers)



Figure 10. Unnotified ZAMST Finger Wrap Single (for sprained finger)



Figure 11. Unnotified ZAMST Arm Sleeves (Compression and Support)

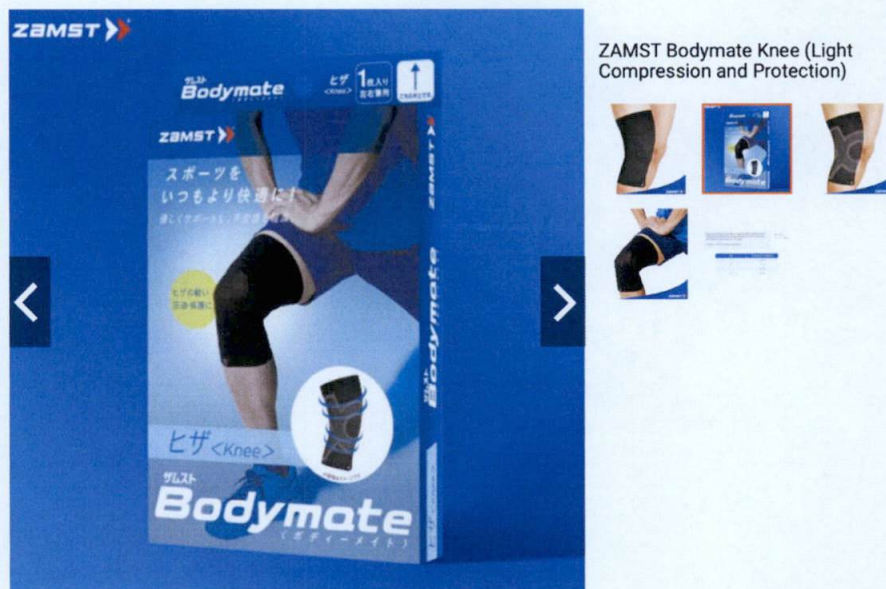


Figure 12. Unnotified ZAMST Bodymate Knee (Light Compression and Protection)



Figure 13. Unnotified ZAMST EK-3 (Compression and Protection)



ZAMST ZW-5 (Moderate Back Support with 3D Back Panel)



Figure 14. Unnotified ZAMST ZW-5 (Moderate Back Support with 3D Back Panel)



ZAMST Thumb Guard (with custom fit)



Figure 15. Unnotified ZAMST Thumb Guard (with custom fit)



ZAMST IW-2 Set (for shoulder and back)



Figure 16. Unnotified ZAMST IW-2 Set (for shoulder and back)



Figure 17. Unnotified ZAMST Footcraft Agility Grip (Functional Insoles)



Figure 18. Unnotified ZAMST Filmista Thigh (New Generation Ultrathin Thigh Support)



Figure 19. Unnotified ZAMST JK-2 (advanced moderate support for patellar tendon and patella)





ZAMST JK-1 (Patellar Tendon and Patella Support)



Figure 20. Unnotified ZAMST JK-1 (Patellar Tendon and Patella Support)



ZAMST Footcraft Standard (Functional Insoles)



Figure 21. Unnotified ZAMST Footcraft Standard (Functional Insoles)



ZAMST Bodymate Wrist (Light Compression and Protection)



Figure 22. Unnotified ZAMST Bodymate Wrist (Light Compression and Protection)

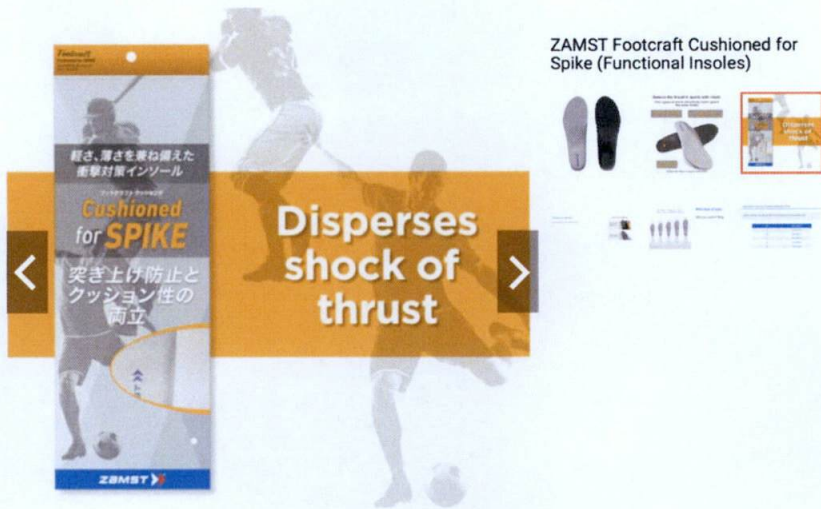


Figure 23. Unnotified ZAMST Footcraft Cushioned for Spike (Functional Insoles)



Figure 24. Unnotified ZAMST Thumb Guard Soft



Figure 25. Unnotified ZAMST EK-5 (Lateral / Medial Stabilization)



ZAMST Shoulder Wrap (light compression and protection)



Figure 26. Unnotified ZAMST Shoulder Wrap (light compression and protection)



ZAMST Bodymate Calf (Light Compression and protection)



Figure 27. Unnotified ZAMST Bodymate Calf (Light Compression and protection)



ZAMST Calf and Ankle Sleeves (Compression and Protection)



Figure 28. Unnotified ZAMST Calf and Ankle Sleeves (Compression and Protection)



ZAMST Filmista Calf (New Generation Ultrathin Calf Support)



Figure 29. Unnotified ZAMST Filmista Calf (New Generation Ultrathin Calf Support)



ZAMST Filmista Wrist (New Generation Ultrathin Wrist Support)



Figure 30. Unnotified ZAMST Filmista Wrist (New Generation Ultrathin Wrist Support)



ZAMST Elbow Band (for elbow trouble with golf and tennis)



Figure 31. Unnotified ZAMST Elbow Band (for elbow trouble with golf and tennis)



ZAMST RK-1 (for Iliotibial Band Syndrome)



Figure 32. Unnotified ZAMST RK-1 (for Iliotibial Band Syndrome)



Zamst Bodymate Ankle (Light Compression and Protection)



Figure 33. Unnotified ZAMST Bodymate Ankle (Light Compression and Protection)



ZAMST AT-1 (for Achilles Tendon)



Figure 34. Unnotified ZAMST AT-1 (for Achilles Tendon)



ZAMST ZW-7 (Strong and Firm back support with 3D Back Panel)



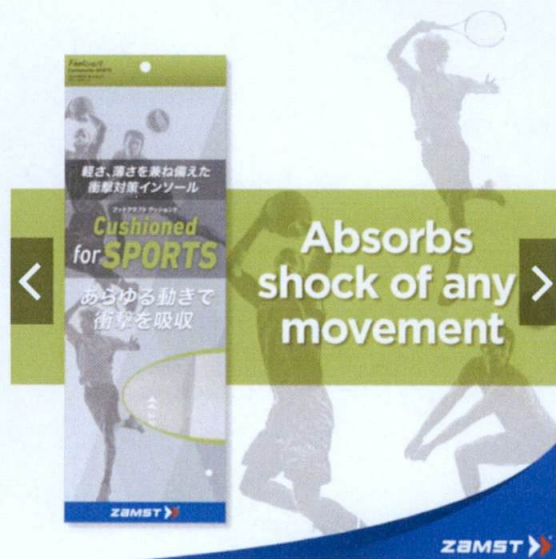
Figure 35. Unnotified ZAMST ZW-7 (Strong and Firm back support with 3D Back Panel)



Zamst Elbow Sleeve (Sleeve-Style Elbow Support)



Figure 36. Unnotified ZAMST Elbow Sleeve (Sleeve-Style Elbow Support)



ZAMST Footcraft Cushioned for Sports (Functional Insoles)



Figure 37. Unnotified ZAMST Footcraft Cushioned for Sports (Functional Insoles)



ZAMST ZK-3 (for sprains of the LCL and MCL)



Figure 38. Unnotified ZAMST ZK-3 (for sprains of the LCL and MCL)



ZAMST IW-1 Set (Icing System with 1 Ice Bag)



Figure 39. Unnotified ZAMST IW-1 Set (Icing System with 1 Ice Bag)



ZAMST Calf Sleeves (Compression and Support)



Figure 40. Unnotified ZAMST Calf Sleeves (Compression and Support)

The FDA verified through post-marketing surveillance that the above mentioned 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](http://www.fda.gov.ph). You may also look for the FDA Registration 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](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

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