

Urgent Field Safety Notice

22nd August 2023

Product Recall due to missing Latex labelling within packaging.

AFFECTED PRODUCTS

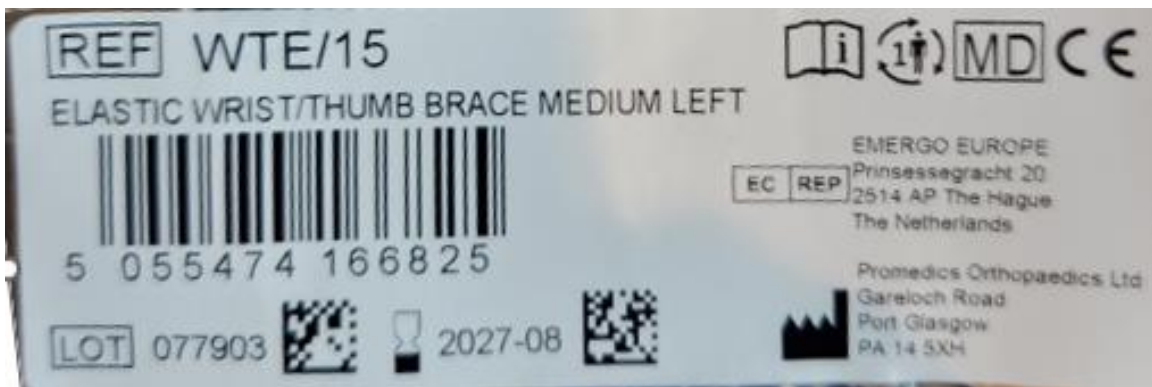
Product Code	Product Description	UDI (GTIN)
WTE/12	ELASTIC WRIST/THUMB BRACE X SMALL LEFT	5055474130857
WTE/13	ELASTIC WRIST/THUMB BRACE SMALL LEFT	5055474130864
WTE/15	ELASTIC WRIST/THUMB BRACE MEDIUM LEFT	5055474166825
WTE/17	ELASTIC WRIST/THUMB BRACE LARGE LEFT	5055474166832
WTE/18	ELASTIC WRIST/THUMB BRACE EX LARGE LEFT	5055474166849
WTE/22	ELASTIC WRIST/THUMB BRACE X SMALL RIGHT	5055474130871
WTE/23	ELASTIC WRIST/THUMB BRACE SMALL RIGHT	5055474130888
WTE/25	ELASTIC WRIST/THUMB BRACE MEDIUM RIGHT	5055474130895
WTE/27	ELASTIC WRIST/THUMB BRACE LARGE RIGHT	5055474166856
WTE/28	ELASTIC WRIST THUMB BRACE X LARGE RIGHT	5055474166863

Dear Sir or Madam,

Today, we would like to inform you about the product recall of a small number of our Elastic Wrist/Thumb Brace products as listed above.

A number of products within the batches listed below had been mislabelled without the Latex warning displayed on/within the product packaging. This only affects the products listed above with the label format and lot numbers shown below.

Lot Numbers: 075213, 077370, 077903, 077990, 078102, 078448



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All current despatches have the correct labelling format as shown below and are immediately available.

Correct Labelling is

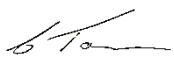


We are committed to providing safe, high-quality medical devices to our customers. Whilst we have not received any reports of injury related to this omission, we are recalling affected products. Please check your current stocks of these batches within your organization and inform all employees who use the products about this Field Safety Notice and confirm that you are not using the affected products.

Please acknowledge your receipt of this FSA by contacting our Customer Services Manager with your inventory check results and he will assist in the information for the return of the products you may have in stock. The products will be uplifted and exchanged free of charge or credited on request.

We thank you in advance for your cooperation and apologise for any inconvenience.

Please contact our Customer Services Manager john.gemmell@promedics.co.uk



Cornelius Toner
Quality Manager

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