

ATTENTION FIELD SAFETY NOTICE – URGENT  
 REF NC 25588  
 PRODUCT Cotton Stretch Crepe Bandage

12/12/2016

Dear Sir/Madam,  
 Please be advised that Synergy Health [UK] Ltd has identified a quality issue with the product listed below. Synergy Health [UK] Ltd has notified the appropriate Regulatory Agency.

Product Code	Product Description	LOT Numbers
28401	Cotton Stretch Crepe Bandage	0816S908, 1016S908, 1616S908, 2616S908, 3016S908, 3416S908
28402		
28403		
28404		

**Description of the problem:**

Synergy Health [UK] Ltd has been advised that the listed products in this document do not meet sterility requirements. The root cause has been determined to be that the supplier did not adequately manage a change in location of crepe bandage manufacture. Unstable bioburden has been demonstrated at this site. There have been no reported adverse incidents from using the product. If you have any concerns regarding product that you may have already used, please contact us on the details provided overleaf.

**Field Safety Notice Actions:**

- All products as listed above should be quarantined immediately.
- Please complete and return a receipt acknowledgement of this notice.
- To arrange collection and replacement of affected stock, please contact the Synergy Health [UK] Ltd Customer Services Department on Tel: +44 [0] 1772 299 999.

**Communication of this Field Safety Notification within your organisation:**

We advise that this notice should be passed on to all those who need to be aware within your organisation, including any organisation where the potentially affected devices have been transferred. Please maintain awareness of this notice until all required actions have been completed in your organisation.

We appreciate your cooperation and apologise for any inconvenience this may cause. We value our relationship with you and trust that with your cooperation this issue shall be resolved. If you have any further questions or concerns, please do not hesitate to contact your customer service representative.

Signed on behalf of Synergy Health [UK] Ltd;

*Nancy Neilson 12 Dec 2016.*  
 Nancy Neilson  
 HCS Quality Manager

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