

# SHANGHAI CHANNELMED IMPORT & EXPORT CO.,LTD

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## URGENT FIELD SAFETY NOTICE

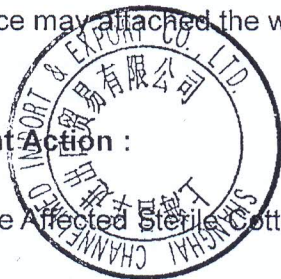
### STERILE COTTON BALLS

Type of Action : Removal

Date : Jan.24,2017

Ref : 201701-2

1. **Manufacturer** : Shanghai Channelmed Import and Export Co., Ltd.
2. **Device Type** : Single-use Devices
3. **Description** : Sterile Cotton Balls 1Gram/Pc, 5 Pcs/Pouch + Photo
4. **Reason of Field Safety Correction Action** :  
The Saudi Food And Drugs Authority reflect the problem that the Sterile Cotton Balls products found impurities, dust particles, plankton, insect inside.
5. **Affected Code Information** : Lot No. : CJ14174, Lot No.: CJ15280, Lot No. : CJ12622, LOT NO.:CJ14361, LOT NO.:CJ14273 & LOT NO.,CJ15023.
6. **Reason of the Problem Causes** :  
Debris falling on cotton ball during the packaging process cause the Sterile Cotton Ball found impurities, dust particles, plankton, insect inside.
7. **Potential Hazard** :
  1. if use the Sterile cotton ball which have dust, plankton and insect, the impurity substance may attached the wound.and the wound may be healed slowly.
8. **The Current Action** :
  - Discard the Affected Sterile Cotton Ball and give compensation to the customers free. .



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Please ensure that the information in this notice is made available to all affected technical aid centers, service companies and dealers within your organization, and that the advice stated in these Manuals is adhered to.

**9. Future Action :**

- Manufacturer should strictly Control Each Process to the Quality during the production and packaging.
- Manufacturer should add inspection procedure , and discard the unqualified products.

**10. Confirmation of National Competent Authorities :**

Please kindly note that this recall is made with the cooperation of Saudi Food and Drugs Authority because there are some remarks on the product,.

Date : Jan.24,2017

