

# SHANGHAI CHANNELMED IMPORT & EXPORT CO.,LTD

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EF015 European Form	FIELD SAFETY NOTICE	PAGE 1 OF 2
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## URGENT FIELD SAFETY NOTICE

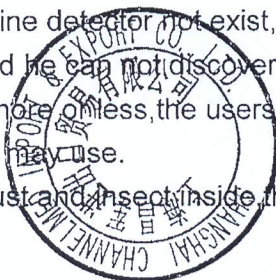
### STERILE GAUZE SWAB WITH X-RAY 4"X4"

Type of Action : Removal

Date : Jan.24,2017

Ref : 201701-1

1. **Manufacturer** : Shanghai Channelmed Import and Export Co., Ltd.
2. **Device Type** : Single-use Devices
3. **Description** : Sterile Gauze Swabs with X-Ray 4" x 4" 16 Ply, 10pcs/pkt + Photo
4. **Reason of Field Safety Correction Action** :  
The Saudi Food And Drugs Authority reflect the problem that the Sterile Gauze Swab with X-Ray products found those problem as below:
  1. Impurities, dust particles, plankton, insect inside
  2. Quantity inside each packet not fixed some times less or more than 10 pieces
  3. Some of the piece of X-Ray gauze did not have X-Ray line detector inside.
5. **Affected Code Information : Lot No.** : 0020114-CJ14128 & 0020114-CJ14148  
14558 & 14364 & 3760811&15216
6. **Potential Hazard** :
  1. If forget the blue line detector not exist, the operating surgeon may use the Gauze swab for the operations and he can not discover it by X-Ray.
  2. If the quantity is more or less, the users can not prepare the correct quantities of Gauze swab which them may use.
  3. If plankton and dust and insect inside, the impurity substance may attached the wound.



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EF015 European Form	FIELD SAFETY NOTICE	PAGE 2 OF 2
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## 7. The Current Action :

- Please discard the affected Sterile Gauze Swab with X-Ray products and give compensation to customers free.

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.

## 8. Future Action :

1. We are trying to use new looms, and use the new type of gauze folding machine and it will avoid the debris falling.
2. We will add automatic weighing procedure by measuring machine to confirm the quantities of pieces after artificial calculation.
3. We will check it carefully during packaging process, and discard those pieces which do not have X-Ray line detector.

## 9. 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