Class 2 Recall
Centurion Sterile 84 Rubber Bands

Date Posted
December 06, 2013

Recall Status
Open

Recall Number
Z-0464-2014

Product
Centurion Sterile # 84 Rubber Bands Reorder EB84. Caution: This product contains natural rubber latex which may cause allergic reactions. LATEX FREE. CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN Single Use Only bands item together and podiatry office uses bands as louriquet on toe during in grown toenail procedure

Code Information
EB84, Lot 2013041801 Expiration 2018/03

Recalling Firm/
Manufacturer
Centurion Medical Products Corporation
301 Catrell Dr
Howell, Michigan 48843-1703

For Additional
Information Contact
Matthew K. Price
517-546-5400

Manufacturer Reason
for Recall
Package labeling indicates both "latex free" and "contains natural rubber latex". The rubber bands do contain natural rubber latex. This could cause a significant risk to users with latex allergies.

FDA Determined
Cause
MISBRANDING: Labeling False and Misleading

Action
Centurion sent a Urgent Recall Notification letter via Certified Mail October 31, 2013, return receipt to all affected customers. The affected Centurion Medical Products Corporation sales representatives were notified via email on October 28, 2013. Customers were instructed to destroy all implicated product and complete the accountability record included with the notice and fax to 517-546-3356. Customers were asked to forward a copy of the notice if product was further distributed. Additional notices will be mailed to non-responsive customers via Certified Mail Return Receipt, and will be documented in the recall file. For further questions please call (517) 546-5400.

Quantity in Commerce
500 lots

Distribution
US Distribution including the states of GA, LA and NY.

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 87.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.