### Class 2 Recall
**Ambitex NMD400 Nitrile Exam Gloves**

**Date Posted:** October 16, 2015  
**Recall Status:** Open  
**Recall Number:** Z-0133-2016  
**Recall Event ID:** 7207824  
**Product Classification:** Polymer Patient Examination Glove - Product Code LZA  
**Product:** Ambitex NMD400 Nitrile Exam Gloves size medium. General Hospital and Personal use. Intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.  
**Code Information:** Ambitex NMD400 Nitrile Exam Glove LOT NUMBER: 25314  
**Recalling Firm/Manufacturer:** Cardinal Health  
1300 Waukegan Rd  
Waukegan, Illinois 60085-6724  
**For Additional Information Contact:** Michele Donatch  
847-887-6412  
**Manufacturer Reason for Recall:** Ambitex NMD400 Exam Gloves size medium on exam hold were inadvertently placed into commerce. The product was under Exam Hold because samples pulled from a shipment manufactured by the firm failed the water leak test performed by FDA as described at 21 CFR 800.20.  
**Action:** The firm sent an Urgent: Product Recall letter dated 8/25/2015. The firm is requesting the user discontinue using and return any remaining stock of the AMBITEX Nitrile Exam Gloves because the gloves were inadvertently shipped prior to U.S. FDA releasing them for sale. Additionally, the firm requests that the customer quarantine the affected examination gloves; and return a copy of the enclosed Acknowledgment Form confirming their receipt of the Urgent recall via fax to 216-651-9760. Customer Service should be contacted at 800-GLOVES-0 to arrange for the return and credit of any on hand product that customer may have. If the customer has further distributed the affected gloves they are advised to notify their customers of the recall.  
**Quantity in Commerce:** 34 cases.  
**Distribution:** Nationwide Distribution.  
**Total Product Life Cycle:** TPLC Device Report

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

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**Links on this page:**  
3. [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)

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11/3/2015