Class 2 Recall Ambitex NMD400 Nitrile Exam Gloves

See Related Information[23]

Date Posted	October 16, 2015
Recall Status[1]	Open
Recall Number	Z-0133-2016
Recall Event ID	72078[24]
Product Classification	Polymer Patient Examination Glove[25] - **Product Code** LZA[26]
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 Donatich 847-887-6412
Manufacturer Reason for Recall	Ambitex Nitrile 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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]