Class 2 Device Recall Fisherbrand Sterile Swabs

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See Related Information[21]

Date Posted	August 12, 2013
Recall Status[1]	Open
Recall Number	Z-1955-2013
Recall Event ID	65822[22]
Product Classification	Applicator, Absorbent Tipped, Sterile[23] - **Product Code** KXG[24]
Product	Fisherbrand Sterile Swab, Calcium Alginate Fiber Tipped, Wood Applicator Swab 100 pouches/boxes, 10 boxes/case. Used in applying medications to or take specimens from a patient.
Code Information	Product code # 14-959-81, lot #61513, expiration date: 2014-08, and lot 8710, expiration date 2014-08.
Recalling Firm/ Manufacturer	Fisher Scientific Co 300 Industry Dr Pittsburgh, Pennsylvania 15275-1001
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Fisher Scientific Co. Customer Service 724-517-1500
Manufacturer Reason for Recall	The firm is recalling Fisherbrand Sterile Swabs due to 4 customer complaints reporting the presence of non-pathogenic organisms in two lots. The finding was confirmed in lot 61513 and lot 8710 is also being recalled as a precautionary measure.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	Customers were notified by letter on June 18, 2013 and requested to discontinue use and return all affected product. The firm also asked that any additional affected customer base be contacted and notified of the recall if the lots had been further distributed. If you have any questions, contact Stericycle (reference "Event 4070") at 1-877-410-5558.
Quantity in Commerce	1230
Distribution	Nationwide and the country of Canada.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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