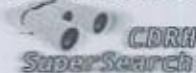


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

## Class 2 Device Recall Fisherbrand Sterile Swabs

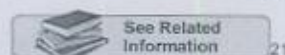


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup>  
 CFR Title 21<sup>15</sup> | Radiation-Emitting Products<sup>16</sup> | X-Ray Assembler<sup>17</sup> | Medsun Reports<sup>18</sup> | CLIA<sup>19</sup> | TPLC<sup>20</sup>

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### Class 2 Recall Fisherbrand Sterile Swabs



<b>Date Posted</b>	August 12, 2013
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1955-2013
<b>Recall Event ID</b>	<a href="#">65822<sup>22</sup></a>
<b>Product Classification</b>	Applicator, Absorbent Tipped, Sterile <sup>23</sup> - Product Code KXG <sup>24</sup>
<b>Product</b>	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.
<b>Code Information</b>	Product code # 14-959-81, lot #61513, expiration date: 2014-08, and lot 8710, expiration date 2014-08.
<b>Recalling Firm/ Manufacturer</b>	Fisher Scientific Co 300 Industry Dr Pittsburgh, Pennsylvania 15275-1001
<b>Consumer Instructions</b>	Contact the recalling firm for information
<b>For Additional Information Contact</b>	Fisher Scientific Co, Customer Service 724-517-1500
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
<b>Action</b>	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.
<b>Quantity in Commerce</b>	1230
<b>Distribution</b>	Nationwide and the country of Canada.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>25</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>26</sup>](#)

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

#### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>