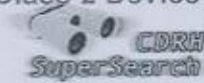


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## Class 2 Device Recall Esmark Elastic Bandage

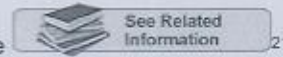


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup>  
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### Class 2 Recall Esmark Elastic Bandage



<b>Date Posted</b>	May 21, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1649-2014
<b>Recall Event ID</b>	<a href="#">67858<sup>22</sup></a>
<b>Product Classification</b>	Bandage, Elastic <sup>23</sup> - Product Code FQM <sup>24</sup>
<b>Product</b>	Individually wrapped Esmark Elastic Bandage (Sterile), 4" x 9', 20 bandages per case. Packaged by Medline Industries Inc., Mundelein, IL 60060. This product is used as an elastic bandage to support and compress a part of a patient's body. It is also used as a tourniquet to restrict blood flow to a part of a patient's body.
<b>Code Information</b>	Product Number: DYNJ05116A . Lot Number: 13LA1009.
<b>Recalling Firm/ Manufacturer</b>	Medline Industries Inc 1 Medline Pl Mundelein, Illinois 60060-4485
<b>For Additional Information Contact</b>	Ms. Cassandra Cotner 866-359-1704
<b>Manufacturer Reason for Recall</b>	Medline Industries, Inc. is voluntarily recalling item DYNJ05116A, Esmark Elastic Bandage (Sterile), 4" x 9', with lot number 13LA1009 that did not go through the correct sterilization procedures. This product may potentially be non-sterile.
<b>FDA Determined Cause<sup>2</sup></b>	TRAINING: Employee Error
<b>Action</b>	Medline Industries issued an Immediate Action Required letter dated March 20, 2014 to all affected customers. The letters included instructions to: 1) immediately check inventories for the recalled products and quarantine the recalled products; 2) complete and return the enclosed destruction form listing the quantity of destroyed product (credit will only be issued if the completed form is received); and 3) If the customer is a distributor, promptly notify the distributor's customers that may have received the recalled products about this recall. Direct accounts and their customers that have any questions can contact Medline Industries at 866-359-1704.
<b>Quantity in Commerce</b>	2,860 bandages
<b>Distribution</b>	Nationwide Distribution including AZ, CA, IA, IL, IN, KY, LA, MI, MS, NJ, NY, OH, PA, TX, and WA.
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>25</sup>

<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.

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>