

U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

Children's Medical Ventures, Gel-E Donut and Squishon 2 - Possibility of Mold

Recall Class: Class I

Date Recall Initiated: May 28, 2014

Products	Model Numbers
Gel-E Donut	92025-A 92025-B 92025-C
Squishon 2	91033-2

The affected products were manufactured and distributed from July 1, 2012 to December 31, 2013.

Use: The Gel-E Donut and Squishon 2 gel-filled products are used in hospitals, under the supervision of a caregiver, to support and cradle an infant's head and/or body. The round shape of the Gel-E Donut helps ease pressure caused by long periods of stillness or other conditions where frequent moving is not suggested. The rectangular shape of the Squishon 2 provides effective abdominal support when lying face downward (prone position) and allows for head movement while maintaining a supportive surface.

Recalling Firm:

Children's Medical Ventures
191 Wyngate Drive
Monroeville, Pennsylvania 15146

Reason for Recall:

Children's Medical Ventures received a number of complaints about visible mold on the outer surface of Gel-E Donut and Squishon 2 gel-filled products. The detected mold was determined to be *Cladosporium* and *Penicillium Fungi*, commonly found molds. *Cladosporium* has been known to cause several different types of invasive infections, including skin, eye, sinus, and brain infections especially in vulnerable populations such as neonates, critically ill patients, and patients with an impaired or weakened immune system. *Cladosporium* and *Penicillium Fungi* can also cause difficulty in breathing or allergic reaction.

The use of affected product may cause serious adverse health consequences, including death.

Public Contact: For questions about this recall, contact Children's Medical Ventures Customer Support at 412-380-8881.

FDA District: Philadelphia District Office

More Information about this Recall:

On May 28, 2014, Children's Medical Ventures sent an "Urgent – Field Safety Notice" informing affected customers, end users, and distributors of the problem, actions that should be taken by the customer/product user in order to prevent risks to patients, and the actions planned by Philips/Children's Medical Ventures to correct the problem.

Children's Medical Ventures provided the following instructions for **customers/product users**:

1. Please review your entire inventory of Gel-E Donut and Squishon 2 products and inspect each product for signs of visible mold. Mold should be readily seen as black dots or splotches through the transparent outer packaging. Please do not open the packaging to do the inspection. If you are unsure or if the inspection is inconclusive, please err on the side of caution and designate that product as containing mold.
2. Use the reply form and document the following information:
 - The total number of each part number in your inventory.
 - The number of each part number found to have visible mold.
 - Your contact information.
3. Dispose of any product containing mold per your facility's environmental guidelines and return unaffected product to your inventory. Please do not return any product to your Distributor or to Philips/Children's Medical Ventures.
4. Customers should sign and date the form and send it to your Distributor. Product users should scan and email the form to gelrecall@philips.com (<mailto:gelrecall@philips.com>), or fax it to +1 404-855-4900.

Children's Medical Ventures provided the following instructions for **distributors**:

1. Determine which of your customers may have affected product.
2. Provide your customers with a copy of the customer letter. The letter asks customers to review their entire inventory of Gel-E Donut and Squishon 2 products and inspect each product for signs of visible mold. Mold should be readily seen as black dots or splotches through the transparent outer packaging. Customers should not open the packaging to do the inspection. If your customer is unsure or if the inspection is inconclusive, please have them err on the side of caution and designate that product as containing mold. A reply form is provided for your customer to respond to you regarding this issue.
3. Your customers are asked to dispose of any product containing mold per their facility's environmental guidelines and return unaffected product to their inventory. Please do not return any product to Philips/Children's Medical Ventures.
4. Once you have received a reply from your customer, use the reply form and document the following information for your customer:
 - The total number of each part number in your customer's inventory.
 - The number of each part number in your customer's inventory found to have visible mold.
 - Your contact information.
5. Sign and date the form, then scan and email it to gelrecall@philips.com (<mailto:gelrecall@philips.com>) or fax it to +1 404-855-4900. If you have distributed product to multiple customers, it is suggested that the reply forms be reserved and sent in once you have received all responses. To ensure that credit is applied to your account correctly, we would appreciate one reply form for each of your customers.

6. Once you receive credit from Philips/Children's Medical Ventures for affected product, provide your customers with credit for product scrapped.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/>) either online, by regular mail or by FAX.