



# RECALL INDEX

**Q1 2019**

**Stericycle Expert Solutions** helps partners minimize risk to the public and to their company brand by executing and planning for product recalls efficiently, effectively, and compliantly.

Each quarter, we analyze cumulative recall data across five product categories. This helps our partners **navigate the regulatory environment and identify trends.**



# MEDICAL DEVICE

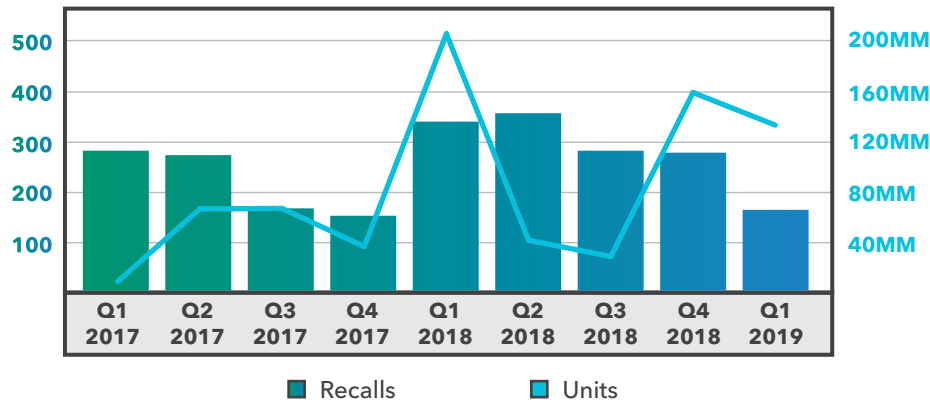
## THE BOTTOM LINE

- ✓ The average recall size was 823,126 - the highest quarter since 2006.
- ✓ At 51.2%, quality issues were the top cause based on units, mostly due to one large recall. This is the first time quality issues were the top cause since Q3 2016.
- ✓ No company reported ten or more recalls in the quarter for the first time since Q3 2017.

# THE STATS

Medical device recalls decreased 41.4% to 164 - the lowest since Q4 2017 and second lowest since Q4 2011. Recalled units decreased 16.2% to just under 135 million - the third highest since at least 2005.

## MEDICAL DEVICE RECALLS & UNITS



## CLASS I UNITS RECALLED PER QUARTER

14,035,195

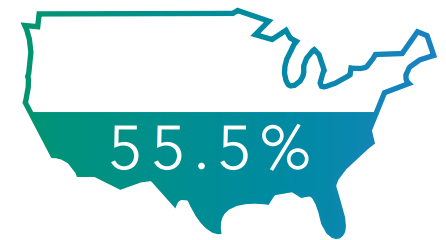
Q3 2018

1,380,706

Q4 2018

1,388,655

Q1 2019



OF MEDICAL DEVICE RECALLS WERE NATIONWIDE

## DID YOU KNOW?

**Medical Device Maladies** \ There were more than **1 million** Class I units recalled for the **third consecutive quarter**. The last time there were three consecutive quarters with at least 1 million units each was Q2 to Q4 2014.

## TOP MEDICAL DEVICE CAUSES BASED ON RECALLS



Software Issue  
37



Mislabeling Issue  
31



Quality Issue  
21



Sterility  
15

# RECALL INDEX EXPLAINED

## HOW THE STERICYCLE RECALL INDEX IS COMPILED

The Stericycle Recall Index gathers and tracks cumulative data from the four primary federal agencies that oversee recalls in the United States: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and the National Highway Traffic Safety Administration (NHTSA).

### FDA DATA

To track trends in food, pharmaceutical, and medical device recalls, the Stericycle Recall Index uses information publicly available in news releases posted on the FDA website. For additional insight into recalls governed by the FDA, Stericycle collects and analyzes data from the agency's weekly enforcement reports, which provide additional details including recall class, quantity of units affected, and number of reported incidents.

### CPSC DATA

For further insight into consumer product recall trends, Stericycle analyzes data from CPSC recall announcements. When compiling statistics and analyzing trends for consumer product recalls, the Stericycle Recall Index uses standard product categories and hazards recognized by the CPSC.

## USDA DATA

For additional insight into food recall trends involving meat, poultry, and egg products, the Stericycle Recall Index collects and analyzes data from recall announcements posted on the USDA's FSIS website. Statistics and trends are compiled using standard product categories, classifications, and reasons for recalls as recognized by the USDA.

### NHTSA DATA

To understand trends in the automotive industry, the Stericycle Recall Index analyzes data from NHTSA reports on recalls of autos, child seats, equipment, and tires.

## TERMINOLOGY

Announced recalls represent those recalls documented in news releases published on agency websites. Enforced recalls refer to those recalls documented in weekly FDA enforcement reports that are summarized based on the FDA assigned Event ID. Their documentation can lag behind announced recalls by weeks or even months because the recall process may take time to complete.



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**We protect what matters.**