# URGENT MEDICAL DEVICE RECALL

Dear Valued Medline Customer:

Medline Industries LP is issuing a product recall for specific Lot Numbers of the Bariatric Rollator, Basic Steel Burgundy and Bariatric Rollator, Basic Steel Blue due to customer reports of the front fork stem bolt/wheel assembly disconnecting from the rollator frame tubing. If the front fork stem bolt/wheel assembly disconnects from the rollator frame tubing, the front wheels may become loose or detach from the rollator.

**Affected Product**:

| Product Number/SKU | Product Description | Lot Numbers |
|---|---|---|
| **MDS86800XWS** | Rollator, Bariatric, Basic Steel, Burgundy | 05425090001<br>05425120001<br>05426010001<br>05426020001<br>05426030001<br>05426040001<br>05426050001 |
| **MDS86800XWBS** | Rollator, Bariatric, Basic Steel, Blue | 05425080001<br>05426040001 |

**Description of the Issue and under what circumstances it can occur:**
The Bariatric Rollator is a mechanical walker with four legs and a metal frame intended for medical purposes to provide moderate weight support while walking. Complaints were received that describe the front fork stem bolt (wheel assembly) disconnecting from the rollator frame tubing and the front wheels becoming loose or detached from the device.

Between August 1, 2025, and June 30, 2026, Medline has received a total of 16 complaints associated with reports of the front fork stem bolt/wheel assembly disconnecting from the rollator frame tubing, or front wheels becoming loose or falling off. There was one report of injury and no reports of death associated with this issue.

**Hazard Involved**

If the front wheels become loose or detach during use, there is risk of severe adverse events. The immediate consequences could include falls resulting in head trauma, bone fractures, or other critical injuries. These events may require emergency medical intervention and hospitalization and in severe cases, could result in death. Long-term health consequences of a fall may include permanent disability, loss of independence, and the need for long-term care.

Confidential – For intended recipients only. Do not Distribute.

**Medline Industries, LP.** Three Lakes Drive Northfield, IL 60093-2753 Toll Free: 866.359.1704 Website: medline.com Email: Recalls@Medline.com Fax: 866.767.1290

**REQUIRED ACTION:**

1. Inspect Your Rollator Immediately
   - Please refer to Image 1: *How to locate and identify the product Lot Number* to locate the front and rear side of the rollator.

   - On the rear side of the rollator, you will find the Lot Label is located on the left side frame tubing, below the seat frame tubing.



**Image 1: How to locate and identify the product Lot Number**

2. If your rollator matches both the affected SKU and an affected Lot Number, immediately discontinue use of the device. Take a clear photograph of the Lot Label and contact Medline Industries, LP directly, as soon as possible. A photograph of the Lot Number must be submitted to Medline for verification. You may contact Medline Industries, LP using one of the following methods:
   - Email: QualityAssurance@medline.com
   - Phone: 1-800-950-0128 option 5

   Once Medline receives and confirms your Lot Number, further instructions regarding discontinued use of the affected rollator will be provided.

Confidential – For intended recipients only. Do not Distribute.

**Medline Industries, LP.** Three Lakes Drive, Northfield, IL 60093-2753 | Toll Free: 866.359.1704 | Website: medline.com | Email: Recalls@Medline.com | Fax: 866.767.1290

3. If your rollator does not have one of the affected Lot Numbers, it may continue to be used in accordance with the Instructions for Use. Please complete and return the attached response form only if you do not have the affected rollator Lot Number.

4. If you have resold, distributed, or transferred this product to another company or individual, FDA regulations require that you notify those recipients of this recall communication. Please contact Medline Industries, LP for further instructions regarding the identification, notification, and handling of affected products distributed to your customers.

**Reporting an Adverse Event**

- Report the event to Medline according to the instructions provided in this notification.
    1. Email: QualityAssurance@medline.com
    2. Phone: 1-800-950-0128 option 5
- Report any serious injury or adverse event associated with use of the circuit in accordance with applicable facility procedures and regulatory reporting requirements.
  Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - Online: By completing and submitting the report **online** at: www.fda.gov/medwatch/report
  - **Regular mail or Fax**: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

If you have any questions, contact the Recall Department at 866-359-1704 or recalls@medline.com.
Please accept our sincere apologies for any inconvenience this may have caused. We, like you, place the health and safety of your patients first and foremost.

Sincerely,
Karin Johnson
Product Recall Coordinator

Confidential – For intended recipients only. Do not Distribute.

**Medline Industries, LP.** Three Lakes Drive Northfield, IL 60093-2753 Toll Free: 866.359.1704 Website: medline.com Email: Recalls@Medline.com Fax: 866.767.1290