

Certified Safety Mfg.

April 04, 2022

URGENT: MEDICAL DEVICE RECALL

First Aid Kits and Cabinets

Containing:

Medi-First XS Aspirin 25/bx

Medi-First Sinus Pain and Pressure 25/bx

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Certified Safety Mfg. is voluntarily recalling specific components found in our First Aid kits and cabinets. The reason for this recall is that our supplier of the Medi-First components has notified our firm that certain lot numbers of the XS Non-Aspirin tablets and the Sinus Pain & Pressure tablets in our First Aid kits and cabinets are potentially contaminated with active pharmaceutical ingredients and are under recall.

Our First Aid kits and cabinets are intended to provide a basic range of products to deal with most common types of injuries including major wounds, minor wounds (cuts and abrasions), minor burns and eye injuries.

Certified Safety Mfg. is requesting that this recall be conducted to the retail level. If you have further distributed these First Aid kits and cabinets to other locations, then you should notify those customers of the recall as well.

It is our policy to provide notification to our customers and provide any recall information available. Please read the information below for details associated with affected First Aid kits and cabinets containing specific lot numbers of Medi-First Sinus Pain and Pressure 25/bx and XS Non-Aspirin 25/box.

Certified Safety requests that all distributors take the following actions:

1. See the list below for part numbers and descriptions to determine whether your kits or cabinets contain recalled lot numbers of Medi-First product.
2. Be certain to request ALL your locations remove any Medi-First product with recalled lot number(s) from kits or cabinets.
3. Remove any Medi-First product with recalled lot number(s) from kits and cabinets which you currently have in stock..
4. Contact Certified Safety Mfg. 816-483-9090 / 800-854-7474 to confirm an RGA number and make return arrangements to our facility.
5. Document all information requested on attached Recall Response Form and return documentation using one of the following:
 - a. Emailing: dgregory@certifiedsafety.com and/or rgauper@certifiedsafety.com
 - b. Fax 800-854-9091 to Certified Safety Mfg. Attn: Robert Gauper
 - c. Using enclosed return envelope mail to:

Certified Safety Mfg.
 Attn: Robert Gauper,
 Quality Assurance Manager
 1400 Chestnut Ave
 Kansas City, Mo. 64127

Product and Distribution Information:

Certified Safety Mfg. First Aid Kits and Cabinets			
Product Name	Product Number	Unique Device Identifier	Distribution Dates
16PW - Firestone Supplemental - w/Logo	K614-020	N/A	7/19 to 8/21
16R - Firestone - Supplemental - Refill	KR614-020	N/A	7/19 to 8/21
36M - Class A Office - Metal	K616-033	(01) 0 07 66588 16033 7	7/19 to 8/21
36R - Class A Office - Refill	KR616-006	(01) 0 07 66588 16006 1	7/19 to 8/21
75R - Class A Office - Refill	KR616-015	(01) 0 07 66588 16015 3	7/19 to 8/21
75V - Class A Office - 3 Shelf Cabinet	K616-015	(01) 0 07 66588 16015 3	7/19 to 8/21
EMT - Duke Energy TD - Red Bag	K618-016	(01) 0 07 66588 18016 8	7/19 to 8/21
EMTR - Duke Energy TD - REFILL	KR618-016	(01) 0 07 66588 18016 8	7/19 to 8/21
FAC-3 - Class B + Meds - 3 Shelf Cabinet	K616-008	(01) 0 07 66588 16008 5	7/19 to 8/21
FAC-3 - Five Star Safety - w/Logo	K618-013	(01) 0 07 66588 18013 7	7/19 to 8/21
FAC-3 - Uline 100 Person - w/Logo	K611-044	(01) 1 08 51253 00762 2	7/19 to 8/21
FAC-3 - Uline Class B + Meds - w/Logo	K620-609	(01) 1 08 51253 00790 5	7/19 to 8/21
FAC-3R - Class B + Meds - Refill	KR616-008	(01) 0 07 66588 16008 5	7/19 to 8/21
FAC-4 - Choate Construction - w/Logo	K616-072	(01) 0 07 66588 16072 6	7/19 to 8/21
FAC-4 - Class B + Meds - 4 Shelf Cabinet	K616-066	(01) 0 07 66588 16066 5	7/19 to 8/21
FAC-4 - Uline - w/Logo - w/CONTENTS STICKER	K612-159	(01) 1 08 51253 00763 9	7/19 to 8/21
FAC-4R - Choate Construction - Refill	KR616-072	(01) 0 07 66588 16072 6	7/19 to 8/21
FAC-4R - Class B + Meds - Refill	KR616-066	(01) 0 07 66588 16066 5	7/19 to 8/21
FAC-5 - Class B - 5 Shelf Cabinet	K616-067	(01) 0 07 66588 16067 2	7/19 to 8/21
FAC-5R - Class B - Refill	KR616-067	(01) 0 07 66588 16067 2	7/19 to 8/21

Certified Safety Mfg. purchases medicinal's through Medi-First and distributes them as a component in First Aid kits and cabinets. Please see the table below for lot numbers that may be found in your First Aid kits and cabinets.

Containing the Following Medi-First Tablets				
Product Name	Product Number	Packet Lot Number	Box Lot Number	Exp. Date (MM/YY)
Sinus Pain & Pressure – 25/2's	81950	6139	6935	09/21
Sinus Pain & Pressure – 25/2's	81950	6428	07332	04/22
Sinus Pain & Pressure – 25/2's	81950	6428	07046	04/22
Sinus Pain & Pressure – 25/2's	81950	6558	07768	07/22
Sinus Pain & Pressure – 25/2's	81950	6558	07741	07/22
Sinus Pain & Pressure – 25/2's	81950	6558	07779	07/22
Sinus Pain & Pressure – 25/2's	81950	6583	08281	08/22
Sinus Pain & Pressure – 25/2's	81950	6641	08586	08/22
Sinus Pain & Pressure – 25/2's	81950	6641	08684	08/22
XS Non-Aspirin – 25/2's	80450	6348	7572	02/22
XS Non-Aspirin – 25/2's	80450	6348	7971	02/22
XS Non-Aspirin – 25/2's	80450	6529	08834	06/22

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Contact Information: Our business hours are as follows: Monday through Thursday, 8:00 AM to 6:30 PM, Central Standard Time.

- a. Call: 816-483-9090 or toll-free 800-854-7474
- b. Email: dgregory@certifiedsafety.com and/or rgauper@certifiedsafety.com
- c. Fax: 800-854-9091 to Certified Safety Mfg. Attn: Robert Gauper
- d. Mail to: Certified Safety Mfg.
Attn: Robert Gauper,
Quality Assurance Manager
1400 Chestnut Ave
Kansas City, Mo. 64127

We appreciate your patience and understanding throughout this unfortunate circumstance. Thank you for your business.

Sincerely



Danny Gregory
Executive Director