Medline International Germany GmbH – Medline Str. 1-3 – D-47533 Kleve

August, 6th 2021

URGENT: FIELD SAFETY CORRECTIVE ACTION

Medical Device Safety Corrective Action

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical Engineering Department.

SECURITY INFORMATION of Medline Sterile stopcocks and manifolds

Medline reference:	**FSCA 21-12**
MoH reference:	
Product Description:	**Medline Sterile stopcocks and manifolds**
Action Type	**Recall**

Dear Customer,

This notification is to inform you that Medline Industries, Inc. has initiated a recall notice. Medline has confirmed a breach in the sterile barrier via pressurization testing of some of our single sterile stopcock and manifold packaging. The investigation, to date, concluded that microscopic pinholes within the sterile pouch could potentially lead to non-sterile conditions. Use of a potentially non-sterile stopcock could lead to a risk of infection, which could be local, or systemic in nature.

REQUIRED ACTION:

1. Immediately check your stock for the affected item number and the affected lot numbers listed on the attachment. Quarantine all affected product.
2. Please destroy all impacted product in your possession and return the completed enclosed response form listing the quantity of affected product on hand. Even if you do not have any affected product please complete and return the form, as indicated on the document.

   When we receive your completed response form, you will receive credit for any affected product reported in your possession or other alternative manifolds can be ordered through customer services.

Medline International Germany GmbH
Medline-Straße 1-3 • 47533 Kleve
Tel: +49 2821 7510 0 • Fax: +49 2821 7510 7802
de-customerservice@medline.com • de.medline.eu

Regulatory Affairs
gmb-eu-fsn-fsca-kleve@medline.com
Tel: +49 (0) 2821 7510 7210 • Fax: +49 (0) 28 21 7510 7822

Geschäftsführer/Legal Director: James D. Abrams • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 204

Manifold Substitute Options:

item RECALLED	Article Description	**Alternative Reference**
64038301	3V STAR OFF MANIFOLD	no alternative
64038303	WMMII 3V 200S RH STR ON	606604045
70015012	SC 4W LP RC OFF R - PG	606000778
70015013	SC 4W LP FM OFF R - PG	606000778
70015015	SC 1W LP RC TEE W - PG	606002617
70035008	SC 3W MP RA/LT OFF PB - PG	606001214
70035009	SC 3W MP RA OFF PB - PG	606001212
70037200	MMII 2V 500S RH OFF PG	60660568
70037202	MMII 2V 500S RH ON PG	no alternative
70037301	MMII 3V 500S RH OFF PG	no alternative
70037303	MMII 3V 500S RH ON PG	60620913
70038200	MMII 2V 200S RH OFF PG	606000741
70038202	MMII 2V 200S RH ON PG	60660823
70038301	MMII 3V 200S RH OFF PG	606001711
70038303	MMII 3V 200S RH ON PG	606608237
70055003	SC 3W HP FM OFF NB - PG	606000410
70055008	SC 3W HP RA/LT OFF NB - PG	no alternative
70055009	SC 3W HP RA OFF NB - PG	60610625925
70055017	SC 1W HP FM TEE NB - PG	656206822

The list of concerned products are listed in TABLE 1 in the acknowledgment form.

The relevant competent authorities have been informed of this safety notice.
Please proceed to the following page to acknowledge receipt of this notice.

Please contact us at the email provided below if you have any questions.
Yours sincerely,

Kenneth Smith
Sr. Manager Regulatory Affairs, Medline Europe

This urgent safety information is only addressed to facilities that have received the products concerned

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Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822
Or send by email to: gmb-eu-fsn-fsca-kleve@medline.com

Reference: FSCA-21/12

Please complete the acknowledgment form and send it back by either fax or email as soon as possible, but no later than September 30th, 2021.

TABLE 1

Medline Item Number (used to purchase)	Lot Number Affected	Individual Quantity Destroyed*

☐ I have read and I understand the instructions provided. I acknowledge receipt of the FSCA-21/12 by signing this document and returning it to Medline.

I also agree to further distribute and communicate this important information within my facility as required.

If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a dealer, wholesaler, distributor/reseller, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above:

Date:	
Account Number:	
Name:	
Position:	
Facility or Business Entity:	
Address:	
City:	
Telephone:	
Fax:	
Signature:	

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