Medline International France
Quality & Regulatory Affairs Dept.
5 Rue Charles Lindbergh
44 110 Châteaubriant

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY CORRECTIVE ACTION
Medical Device Safety Advisory Notice

Châteaubriant, 15th May 2023

ATTENTION:
Pharmacist,
Risk Manager responsible for medical device vigilance,
The Biomedical/Engineering Department.

Security Information regarding Turkuaz Ultrasound Gel included in Medline Probe Covers Kit

Medline Reference:	**FSCA-23/02**
MoH Reference:	**N/A**
Product description:	**Turkuaz Ultrasound Gel included in Medline Probe Covers Kit**
Action type:	**Field Safety Corrective Action**
Product codes :	**See details in the Table 1 of the acknowledgment form**

Dear Customer,

This letter is to advise you that Medline has initiated a field safety corrective action regarding the Ultrasound Gel manufactured by Turkuaz included in Medline Probe Covers Kit.

REASON FOR THE FSCA:

During an inspection performed by Medline, they observed a breach regarding the sterility of the Turkuaz Ultrasound Gel.

Although no serious incidents have been reported, the sterility of the gel cannot be guaranteed.
Therefore, Medline has decided to perform a field safety corrective action FSCA-23/02 regarding the Turkuaz Ultrasound Gel included in Medline Probe Covers Kit.

POTENTIAL RISKS:

The use of this Ultrasound Gel could lead to a potential risk of infection for the patient.

CORRECTIVE ACTIONS:

Medline has taken the decision to stop distributing the Turkuaz Ultrasound Gel and is currently looking for an alternative Gel.

ACTIONS REQUIRED:

Step 1: Please take note of this field safety corrective action and inform all users in your facility.

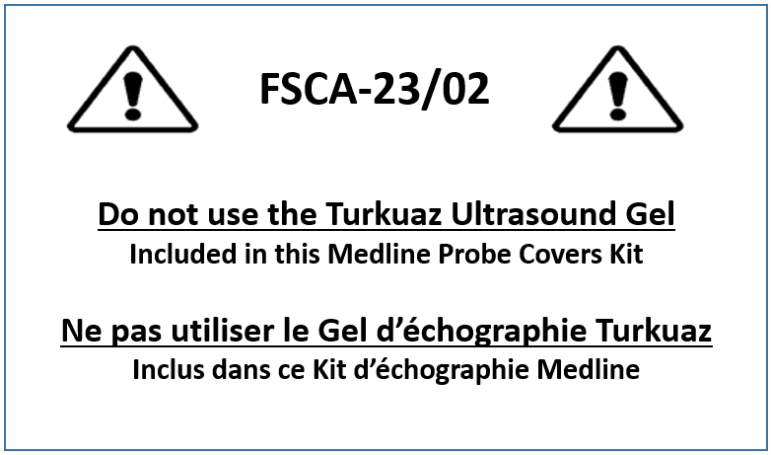
Step 2: Urgently check your stock and promptly put on quarantine the concerned kits listed in Table 1 (see: acknowledgement form).

Step 3: Complete the acknowledgement form and indicate the quantity of impacted kits in your stock, to receive the necessary quantity of "warning stickers" to be placed on each Medline Probe Covers Kit. Then, return the acknowledgement form by email as soon as possible, but not later than **June 2nd, 2023**.

Step 4: Place a "warning sticker" in the middle of each concerned Medline Probe Covers Kit of your stock and on each box under the label.

Step 5: Do not use the affected Turkuaz Ultrasound Gel from your Medline Probe Covers Kit and remove it before use in the operating room.

WARNING STICKER:



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Tel: +33 (0)2 44 05 30 68
gmb-eu-fsn-fsca-chbt@medline.com

We thank you for your cooperation and Medline apologizes for the inconvenience caused. 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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Please email the Acknowledgement Receipt (pages 4 & 5) to the email address: GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSCA-23/02

Please complete the acknowledgement form and send pages 4 and 5 back by email as soon as possible, **but no later than 2nd June 2023**.

Table 1: The Medline Probe Covers Kits which include the Ultrasound Gel concerned by this notification are listed in the below table:

References	Lot Numbers				
ICE5900	20GAHW06	21BAHW05	21KAHW03	22DAHW01	22FAHW02
	20KAHW02	21CAHW05	21KAHW06	22DAHW02	22FAHW04
	20KAHW05	21DAHW05	21LAHW01	22EAHW01	
	20MAHW01	21GAHW02	21MAHW01	22EAHW04	
	20MAHW02	21GAHW03	22AAHW03	22FAHW01	
ICE5910	20GAHW06	21DAHW03	21KAHW05	22CAHW01	22EAHW04
	20HAHW03	21DAHW05	21LAHW02	22CAHW02	22FAHW01
	20JAHW02	21FAHW02	21MAHW01	22DAHW01	22FAHW02
	20KAHW02	21GAHW02	22BAHW01	22DAHW02	22FAHW04
	20MAHW03	21HAHW02	22BAHW02	22EAHW01	22GAHW02
	21AAHW04	21KAHW02	22BAHW03	22EAHW02	
ICE5920	20GAHW06	21CAHW05	21KAHW02	22AAHW03	22FAHW01
	20JAHW02	21DAHW01	21KAHW03	22BAHW01	22FAHW02
	20KAHW02	21DAHW03	21KAHW05	22BAHW02	22FAHW04
	20LAHW05	21EAHW01	21KAHW06	22BAHW03	
	20MAHW03	21FAHW02	21LAHW01	22DAHW01	
	21AAHW02	21GAHW02	21LAHW02	22DAHW02	
	21AAHW03	21GAHW03	21MAH01	22EAHW01	
	21BAHW04	21HAHW01	21MAHW01	22EAHW02	
	21BAHW05	21HAHW02	22AAHW02	22EAHW04	
ICE5930	20JAHW02	21DAHW03	21KAHW03	22CAHW01	22FAHW02
	20LAHW04	21EAHW04	21LAHW01	22CAHW02	22FAHW04
	20MAHW03	21FAHW01	21LAHW02	22DAHW01	
	21CAHW05	21HAHW01	22BAHW02	22DAHW02	
	21DAHW01	21KAHW02	22BAHW03	22FAHW01	

Quantity *(in eaches)* **of stickers needed:** _____

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By completing and signing the document, I confirm that I have read and I understood the instructions provided.
I acknowledge receipt of the FSCA-23/02 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: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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