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

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE
Medical Devices Recall

Châteaubriant, Date

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

Recall for sterile surgical drapes and sterile surgical gowns

Medline Reference:	**FSN-26/01**
ANSM Reference:	**R2600545**
Product description:	**Sterile surgical drapes and sterile surgical gowns**
Legal Manufacturer SRN:	**FR-MF-000000676**
Action type:	**Recall**
Product codes:	**See Appendix 1 and 2 *(pages 4-5)***

Dear Customer,

This letter is to advise you that Medline International France S.A.S. has initiated a Recall regarding sterile surgical drapes and sterile surgical gowns. The impacted products are listed in **Appendix 1 and 2** ***(pages 4-5)***.

The majority of sterile surgical drapes and sterile surgical gowns remain available; your local Medline service representative will provide you with alternatives in case certain products are temporarily not available.

REASON FOR THE RECALL:

Medline determined that one of its suppliers did not adequately document calibrations for sealing equipment and sterilization-related sensors. As a result, although products underwent a validated sterilization cycle, the accuracy of the sterilization data cannot be verified, and the minimum sterility assurance level and the integrity of the sterile barrier over the intended shelf life cannot be assured.

POTENTIAL RISKS:

The sterility of the product is at risk in case of inadequate sealing and/or sterilization methods, which may cause an increased risk of infection during procedures.

ACTIONS REQUIRED:

Step 1: Please take note of this recall and inform all users in your facility.

Step 2: Urgently perform a physical check into your inventory to promptly put on quarantine and discard the impacted products as listed in **Appendix 1 and 2**.

Impacted lot numbers can be quickly identified:

- The two first digits of the lot number are the production year (**25**xx**C**xxx).
- The fifth letter of the lot number must be **C.**

Every lot produced before 2026 (lot numbers starting with **25** – **24** – **23** – **22** and **21**) and having a **C** in the fifth position is concerned by this recall. *For example, lot number **23**AA**C**001 is concerned.*

Note: please ensure to still check the full list of impacted products in **Appendix 1 and 2**.

Step 3: Please complete the Acknowledgment Receipt *(page 3)* and indicate the number of units discarded *(pages 4-5)* in your stock. Then, return pages 3 - 4 and 5 by email as soon as possible **but no later than 27th January 2026**.

Step 4: If you no longer have any of the impacted products in stock, please also complete the Acknowledgment Receipt *(page 3)* and return it by email as soon as possible **but no later than 27th January 2026**.

Step 5: If you have any questions or need support, please contact your Medline Sales Representative or your Medline Local Customer Service.

The relevant competent authorities have been informed of this recall.

Please proceed to the following pages to acknowledge receipt of this notice. Medline apologizes for the inconvenience caused by this recall and would like to thank you for your cooperation.

Yours sincerely,

Willem van Alst,
Sr. Manager Post Market Surveillance, Medline Europe

This urgent and important field safety notice is only addressed to facilities that have received the impacted products.

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Please email the Acknowledgement Receipt to the following email address: GMB-EU-FSN-FSCA-CHBT@medline.com

Medline Reference: FSN-26/01

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than 27th January 2026**.

The products impacted by this recall are listed in Appendix 1 and 2 *(pages 4-5).*

By completing and signing this acknowledgement receipt, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-26/01 by signing this document and returning it to Medline.

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you are **a dealer, wholesaler, distributor/reseller**, that distributed any impacted 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 per email to GMB-EU-FSN-FSCA-KLEVE@medline.com

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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Appendix 1 – Sterile drapes concerned

Reference	Lot numbers	Qty of units discarded
3527CE	Before 26xxCxxx	
3528CE	Before 26xxCxxx	
DYJPEADSSM1	Before 26xxCxxx	
DYJPEARPSM1	Before 26xxCxxx	
DYJPEEXDSM	Before 26xxCxxx	
DYJPEHEDSM2	Before 26xxCxxx	
DYJPEOBPSM	Before 26xxCxxx	
DYJPETUPSM	Before 26xxCxxx	
DYJPEUNMPSM1	Before 26xxCxxx	
DYJPEUNPSM1	Before 26xxCxxx	
DYJPEUNPSM2	Before 26xxCxxx	
DYNJPE9010SM	Before 26xxCxxx	
ES10111CE	Before 26xxCxxx	
ES15003CE	Before 26xxCxxx	
ES15207CEA	Before 26xxCxxx	
ES15209CE	Before 26xxCxxx	
ES15211CE	Before 26xxCxxx	
ES15212CE	Before 26xxCxxx	
ES15213CE	Before 26xxCxxx	
ES15214CE	Before 26xxCxxx	
ES15215CE	Before 26xxCxxx	
ES15216CE	Before 26xxCxxx	
ES15217CE	Before 26xxCxxx	
ES152182CE	Before 26xxCxxx	
ES152183CE	Before 26xxCxxx	
ES15218CE	Before 26xxCxxx	
ES15219CE	Before 26xxCxxx	
ES15221CE	Before 26xxCxxx	
ES15222CE	Before 26xxCxxx	
ES15223CE	Before 26xxCxxx	
ES15225CE	Before 26xxCxxx	

Reference	Lot numbers	Qty of units discarded
ES15226CE	Before 26xxCxxx	
ES15227CE	Before 26xxCxxx	
ES15228CE	Before 26xxCxxx	
ES15303CE	Before 26xxCxxx	
ES15307CE	Before 26xxCxxx	
ES15308CE	Before 26xxCxxx	
ES15310CE	Before 26xxCxxx	
ES15312CE	Before 26xxCxxx	
ES29105CE	Before 26xxCxxx	
ES29176CE	Before 26xxCxxx	
ES29186CE	Before 26xxCxxx	
ES29496CE	Before 26xxCxxx	
ES29540CE	Before 26xxCxxx	
ES29641CE	Before 26xxCxxx	
ES29973CE	Before 26xxCxxx	
ES93585CE	Before 26xxCxxx	
ES9462CE	Before 26xxCxxx	
ESAG3521CE	Before 26xxCxxx	
ESAG3541CE	Before 26xxCxxx	
ESAG3542CE	Before 26xxCxxx	
S7444CE	Before 26xxCxxx	
S9563CE	Before 26xxCxxx	
SM29095CEA	Before 26xxCxxx	
SM29105CE	Before 26xxCxxx	
TB294431CE	Before 26xxCxxx	
TB29496CE	Before 26xxCxxx	
TB9355CEA	Before 26xxCxxx	
TB9358CE	Before 26xxCxxx	
TB9414CE	Before 26xxCxxx	
TB9461CE	Before 26xxCxxx	

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Appendix 2 – Sterile gowns concerned

Reference	Lot numbers	Qty of units discarded
E3500CEA	Before 26xxCxxx	
E3505CEA	Before 26xxCxxx	
E3506CEA	Before 26xxCxxx	
E3510CEA	Before 26xxCxxx	
E3513CE	Before 26xxCxxx	
E3516CEA	Before 26xxCxxx	
E3540CEA	Before 26xxCxxx	
E3545CEA	Before 26xxCxxx	
E3581CE	Before 26xxCxxx	
E3585CEA	Before 26xxCxxx	
E3600CE	Before 26xxCxxx	
E3605CE	Before 26xxCxxx	
E3606CE	Before 26xxCxxx	
E3610CE	Before 26xxCxxx	
E3613CE	Before 26xxCxxx	
E3616CE	Before 26xxCxxx	
E3640CE	Before 26xxCxxx	
E3645CE	Before 26xxCxxx	
E3681CE	Before 26xxCxxx	
E3685CE	Before 26xxCxxx	
NONE27281	Before 26xxCxxx	
NONE27281XL	Before 26xxCxxx	
NONE27281XXL	Before 26xxCxxx	
OP39512CE	Before 26xxCxxx	
OP39516CE	Before 26xxCxxx	
OP9500CE	Before 26xxCxxx	
OP9505CE	Before 26xxCxxx	
OP9506CEA	Before 26xxCxxx	

Reference	Lot numbers	Qty of units discarded
OP9507CEA	Before 26xxCxxx	
OP9508CEA	Before 26xxCxxx	
OP9509CEA	Before 26xxCxxx	
OP9510CE	Before 26xxCxxx	
OP9512CE	Before 26xxCxxx	
OP9513CE	Before 26xxCxxx	
OP9516CEB	Before 26xxCxxx	
OP9540CE	Before 26xxCxxx	
OP9575CE	Before 26xxCxxx	
OP9581CE	Before 26xxCxxx	
OP9583CE	Before 26xxCxxx	
OP9585CE	Before 26xxCxxx	
OP9586CE	Before 26xxCxxx	
OP9588CE	Before 26xxCxxx	
OP9590CE	Before 26xxCxxx	
OP9809CE	Before 26xxCxxx	
OP9812CE	Before 26xxCxxx	
S3505CEC	Before 26xxCxxx	
S3506CEC	Before 26xxCxxx	
S3512CEC	Before 26xxCxxx	
S3513CEB	Before 26xxCxxx	
S3516CEC	Before 26xxCxxx	
S3540CEC	Before 26xxCxxx	
S3545CEC	Before 26xxCxxx	
S3913CE	Before 26xxCxxx	
S3940CE	Before 26xxCxxx	
URO130CE	Before 26xxCxxx	
URO150CE	Before 26xxCxxx	

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