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

Company Name
Address
Address
ZIP City

Kleve, 9. Januar 2025

URGENT: FIELD SAFETY NOTICE
Medical Device Recall

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

Recall for Electrosurgical Electrode distributed by Medline

Medline Reference:	**FSN-24/02**
MoH Reference:	**N/A**
Product description:	**Electrosurgical Electrode**
Legal Manufacturer SRN:	**CN-MF-000006969**
Action type:	**Recall**
Product codes:	**See Annex 1 *(page 5)***

Dear Customer,

UPDATE DECEMBER 2024:

This letter follows the Recall for Electrosurgical Electrode distributed by Medline referenced FSN-24/02 launched in April 2024.
Medline has received additional information from the Legal Manufacturer, QueenMed, stating that additional lot numbers are impacted by this recall.
Therefore, the **Annex 1** *(page 5)* has been updated with the new scope.

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Geschäftsführer/Legal Director: Hervé Bertrand Million, Jochen Helmut Günther Hein • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 204

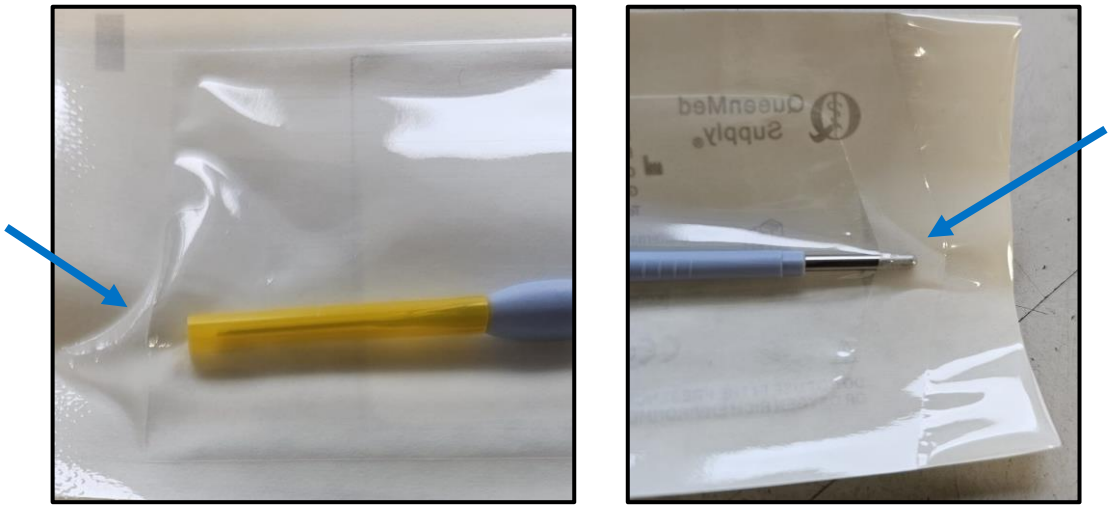
COMMUNICATION APRIL 2024:

This letter is to advise you that Medline has been informed by the Legal Manufacturer, QueenMed, that they have initiated a recall regarding Electrosurgical Electrodes distributed by Medline International France S.A.S, listed in **Annex 1** *(page 5).*

REASON FOR THE RECALL:

Following the receipt of a customer complaint and after investigations, QueenMed issued a recall due to potentially weak seals of the peel pouch packaging that may cause a breach in the sterile barrier. Although no serious incidents have been reported to date, QueenMed is recalling the affected lots in an abundance of caution.

Figure 1: Example of weak seal and breach of sterile barrier



POTENTIAL RISKS:

The product is provided sterile and is used to conduct radio frequency (RF) for cutting and coagulation in broad ranges of surgical procedures requiring the use of electrosurgery. The use of a non-sterile surgical tip electrode can compromise the sterile field, and/or increase the risk of patient infection.

CORRECTIVE ACTIONS:

The legal manufacturer is implementing the following preventive and corrective actions:

- Reinforce tensile force of the sealing machine from 3 to 5 newton on the pouches.
- Addition of packaging foam into the shipper boxes to prevent product movement during transportation.
- Verify packaging and shipping conforms to the ASTM D1469 standard.

ACTIONS REQUIRED:

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

Step 2: Urgently physically check your stock to promptly put on quarantine and discard the concerned Electrosurgical electrodes listed in **Annex 1** *(page 5).*

Step 3: Please complete the Acknowledgment Receipt *(pages 4 & 5)* and indicate the number of units discarded in your stock. Then, return it by email as soon as possible **but not later than January 24th, 2025**.

Step 4: If you no longer have any of the impacted products in stock, please complete the Acknowledgment Receipt *(pages 4 & 5)* and return it by email as soon as possible **but not later than January 24th, 2025**.

COMPENSATION:

Once Medline has received your completed and signed Acknowledgment Receipt, a credit note will be issued for the impacted products discarded in your stock.

Thank you for your cooperation; 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,

Audrey Barraud,
Quality Director, Medline Europe

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

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

Medline Reference: FSN-24/02

Please complete the Acknowledgement Receipt and send it back by email as soon as possible, **but no later than January 24th, 2025**.

The products concerned by this recall are listed in Annex 1 *(page 5).*

By completing and signing the document, I confirm that I have read, and I understood the instructions provided. I acknowledge receipt of the FSN-24/02 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: _____

Annex 1

Reference	Lot Number	Quantities discarded *(in eaches)*
SP200-B100S	Lots inferior of 2414510	
SP200-B200S	Lots inferior of 2413514	
SP200-C101S	Lots inferior of 2444531	
SP200-C201S	Lots inferior of 2420509	
SP200-L31S	Lots inferior of 2416517	
SP200-L35S	Lots inferior of 2416518	
SP200-L36S	Lots inferior of 2416519	
SP200-L37S	Lots inferior of 2416520	
SP200-L45S	Lots inferior of 2416521	
SP200-N100S	Lot 20260913 And lots inferior of 2414504	
SP200-N200S	Lots inferior of 2416512	