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

Company Name
Address
Address
ZIP City
Country

URGENT: FIELD SAFETY NOTICE
Medical Device Recall

Kleve, Date

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:	**R2409446**
Product description:	**Electrosurgical Electrode**
Legal Manufacturer SRN:	**CN-MF-000006969**
Action type:	**Recall**
Product codes:	**See Annex 1 *(page 5)***

Dear Customer,

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).*

Medline International Germany GmbH
Medline-Straße 1-3 • 47533 Kleve
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de-customerservice@medline.com • de.medline.eu

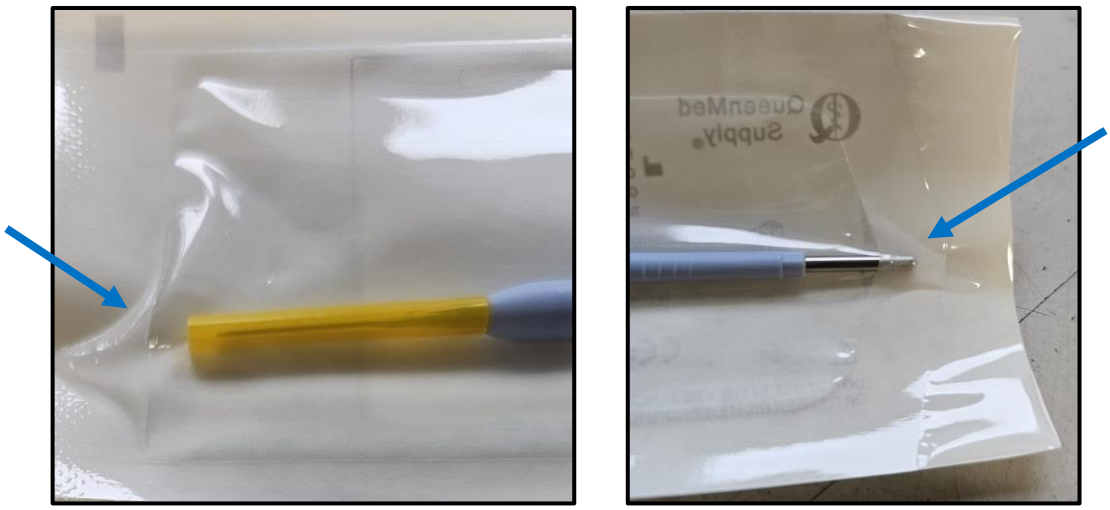
Regulatory Affairs
gmb-eu-FSN-FSCA-kleve@medline.com
Tel: +49 (0) 2821 7510 7122 • Fax: +49 (0) 28 21 7510 7822

Geschäftsführer/Legal Director: James D. Abrams • Registergericht/Registry Court: Handelsregister des Amtsgerichts Kleve HRB 202

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 31st May 2024**.

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 31st May 2024**.

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 31st May 2024**.

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	2227509	
SP200-B200S	2227510	
	2306503	
	2317503	
SP200-C101S	2227508	
	2251505	
	2312501	
	2317505	
	2317508	
	2330513	
SP200-C201S	2341501	
SP200-L31S	2222502	
	2310532	
	2330512	
	2332501	
	2335506	
SP200-L35S	2222503	
	2251509	
	2310529	
	2317504	
	2323501	
	2329503	
	2332502	
	2343505	
SP200-L36S	2332503	
SP200-L37S	2222504	
	2332504	

Reference	Lot Number	Quantities discarded *(in eaches)*
SP200-L45S	2222505	
	2329501	
	2330511	
	2332505	
	2335502	
SP200-N100S	2227511	
	2251504	
	2306504	
	2307503	
	2310531	
	2329502	
	2330510	
	2339501	
	2339502	
	2343504	
	2351505	
	2352520	
	2402525	
SP200-N200S	2227507	
	2317502	
	2317506	
	2343503	