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Address (if needed)

## **URGENT: FIELD SAFETY (CORRECTIVE ACTION) NOTICE**

### **Medical Device Safety Advisory Notice**

Kleve, xxx, 2021

**For the attention of:** the Pharmacist responsible for medical device vigilance and the Biomedical Engineering Department.

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#### **SECURITY INFORMATION of Medline Curad Latex Exam Glove**

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**Medline reference:** FSN 21/06  
**MoH reference:**  
**Description:** Medline Curad Latex Exam Glove  
**Product Codes concerned:** Cure8107 Lot KSS20W11

Dear Customer,

This letter is to advise you that Medline is issuing a field safety notice on Exam Glove reference Cure8107 Lot KSS20W11. No incidents have been reported but this is a precautionary measure. These Exam Gloves are dual certified Medical Devices and Personal Protective Equipment (PPE). This FSN is related to the PPE Certification.

#### **Issues:**

The permeability testing for Hydrogen Peroxide and Formaldehyde did not achieve the claimed levels indicated on the labelling. These Exam Gloves should not be used to handle these chemicals. These Exam Gloves meet all the requirements for EN 455 as a Medical Glove.

#### **Actions to be taken:**

1. Read this Field Safety Notice carefully and communicate this notification to healthcare professionals in your facility.
2. Please complete and send back the enclosed acknowledgment form by either fax or email as soon as possible, but **not later than 4<sup>th</sup> June 2021.**

If requested, Medline will offer different gloves, which are dual certified Medical Devices and Personal Protective Equipment (PPE).

The relevant competent authorities are informed of this safety notice.

We apologize for the inconvenience caused.

Yours Sincerely,  
Kenneth Smith

International Quality and Regulatory Affairs Manager.

PS: This urgent safety information is only addressed to facilities that had received the concerned Gloves.



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**Acknowledgement receipt to fax to the following fax number: +49 2821 7510 7822  
or send by email to: [gmb-eu-ra-kleve@medline.com](mailto:gmb-eu-ra-kleve@medline.com)**

**Medline reference: FSN -21/06**

Please complete and send back the enclosed acknowledgment form by either fax or email to Medline as soon as possible, but no later than **4<sup>th</sup> June, 2021**.

Item number	Lot number
Cure8107	KSS20W11

I have read and understood the security information provided by Medline and I acknowledge receipt of the FSN-21/06.

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, or original equipment manufacturer (OEM) that distributed any affected products to other facilities, please distribute this notification to customers and confirm us that your customers have been notified.

Date: \_\_\_\_\_  
Customer Number: \_\_\_\_\_  
Name: \_\_\_\_\_  
Position: \_\_\_\_\_  
Facility: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_  
Telephone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Signature: \_\_\_\_\_