

## URGENT: FIELD SAFETY CORRECTIVE ACTION NOTICE (End-User Level)

 Date: *enter date here*

Control Number: 6365

Dear Valued Customer,

DE Healthcare Ltd has become aware of a quality issue from our Private-Label manufacturing partner. Investigation determined that this defect was caused by a manufacturing difference between the previous and current approved vendor. Our current vendor uses only an adhesive to attach the bracket to the barrel of the syringe, where-as the previous vendor used both adhesive and a mechanical stop. The mechanical stop for the bracket is not visible on the finished good therefor the precaution was not detected in the pre-production samples provided.

Without the mechanical stop in place, the bracket may become dislodged from the barrel. If the bracket were to fall off during a procedure, there is a remote possibility that it could result in either reduced control of the plunger during Novocain administration or it could present a choking hazard if the bracket were to be aspirated by the patient. Due to performance issues in the field and the potential outcomes identified; we are recalling this product.

**Corrective Action:** Our current vendor will mirror the previous vendor’s manufacturing process (i.e., adhesive, and mechanical stop) for this product code, which will subsequently be evaluated prior to acceptance of the modification.

TABLE A – Affected Product		
Product Code	Product Description	Lot Number
112-1719	Self-Aspirating Syringe Dual Action 2,2ml Non-Metric, DEHP	20210904
		20211125
979-2604	Self-Aspirating Syringe Dual Action Metric 1,8ml DEHP	20210615
		20210904

**Actions Required:**

1. **CHECK** to confirm if you have any units of the affected product/lot number in your possession by utilizing **Table A– Affected Product**.
2. **SEGREGATE and QUARANTINE** all product/lot listed in **Table A– Affected Product**.
3. **RETURN** Only the specified item/lot number listed in **Table A– Affected Product** purchased from DE Healthcare Ltd within **60 days** to the address below. **Please enclose this Field Safety Notification together with the return.** Returns for non-affected items will not be accepted.

**Customers** should return the product to: *Complete the acknowledgement form and a return will be arranged.*

4. **COMPLETE** the enclosed acknowledgment form and return by email [UKAdverseandRecalls@henryschein.co.uk](mailto:UKAdverseandRecalls@henryschein.co.uk). Please respond even if you are not affected by this notification.

If you have further questions, please contact [UKAdverseandRecalls@henryschein.co.uk](mailto:UKAdverseandRecalls@henryschein.co.uk). We recognize the criticality of this issue, and we appreciate your understanding and patience.

Sincerely,

DE Healthcare Ltd

Date: *enter date here*

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**URGENT: FIELD SAFETY CORRECTIVE ACTION NOTICE (End-User Level)  
DE Healthcare Ltd Response Form**

Please note, **only returns of the specified listed item/lots purchased from DE Healthcare Ltd will be credited to your account.** Accounts will not be credited for non-affected products, non-affected lot numbers or any product not purchased from DE Healthcare Ltd. Please include the **completed response form and invoice copy (if available) with your return shipment.** If no return shipment is being processed, please forward this response as instructed below.

PLEASE SHIP AFFECTED PRODUCT TO:	FORWARD <u>RESPONSES ONLY</u> TO: (DO NOT SHIP PRODUCT TO THIS LOCATION)
Follow return instructions outlined in the <b>Action Section</b> of this notification	<p align="center"><b>Email:</b> <a href="mailto:UKAdverseandRecalls@henryschein.co.uk">UKAdverseandRecalls@henryschein.co.uk</a> - Or - <b>Mail:</b> <i>Medcare North, Centurion Close, Gillingham Business Park Gillingham Kent ME8 0SB</i></p>

- We have read and understand the information that has been provided and will follow the necessary instructions to ensure the proper actions will be taken.
- We have checked our inventory and the following affected product has been found. (Please fill in the information below)

Product Code	Lot Number	Quantity

- We have checked our inventory and DO NOT have the specified product in stock.

\_\_\_\_\_  
Print Name and Title

\_\_\_\_\_  
Company Name and Ship to Account #

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date