



PRODUCT RECALL

May 18, 2021

Urgent Field Safety Notice

Baxter Medication Delivery, and Renal Care Products – Third-Party Incomplete Sterilization Reports

Dear Healthcare provider,

Problem Description

Baxter Healthcare was informed by one of our third-party sterilization providers that certain lots of Medication Delivery, Nutrition, and Renal Care products, which are listed in Annex 1 of this notice may not have been properly sterilized, or adequate documentation of sterilization was not provided to Baxter. The risk to patients is that they may have an improperly sterilized product. After a thorough review, Baxter believes the risk to be low, however, to keep patients as safe as possible we are recalling the potentially impacted lots.

Baxter used this third-party provider to sterilize the affected product lots which have been distributed in Saudi Arabia. Only products from the lots listed in Annex 1 are being removed from the market.

Note that other Baxter products or product lots, not listed in Annex 1, may also be in your or your patients' possession. These products are considered safe to use.

Baxter is kindly asking that you take the following actions:

Action to be taken by Customers

1. Locate and remove all affected product from your facility. The product code and lot number can be found on the individual product and shipping carton.
2. Customers may continue to place orders for product lots that are not listed on Annex 1. Contact Baxter Healthcare Customer Service at to order replacement product.
3. Contact Baxter Healthcare Customer Service to arrange for return of the products and credit. Customer Service can be reached at +966547042950 between the hours of 8:00 am to 5:00 PM Please have your ship-to account number ready when calling.
4. Complete the enclosed Baxter Customer Reply Form and return it to Baxter using one of the following options:
 - scanning and e-mailing it to Ahmed.Albalaasi@Baxter.com

Please complete the Reply Form even if you do not have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. This step is required, per regulatory mandates.



5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

The Saudi Food and Drug Authority is informed about this product recall.

If you have additional questions, please contact your Baxter sales representative at +966551048777

Kind regards,

Baxter Healthcare

Enclosure: Annex 1: Affected Product Table
Baxter Customer Reply Form
Home Patient Customer Letter

| Catalogue number | Lot/Batch number(s) | Commercial name/brand name/make |
|------------------|---------------------|--------------------------------------|
| EMC9603 | 16F27T688N | Solution Administration Set |
| EMC9612 | 16G03T065 | Solution or Blood Administration Set |
| EMC9612 | 16I03T694 | Solution or Blood Administration Set |
| EMC9603 | 16I14T705N | Solution Administration Set |
| EMC9612 | 16I27T755 | Solution or Blood Administration Set |
| EMC9603 | 16J18T074N | Solution Administration Set |
| EMC9603 | 16J21T108N | Solution Administration Set |
| EMC9603 | 16J22T078N | Solution Administration Set |
| EMC9603 | 17A09T040N | Solution Administration Set |
| EMC9603 | 17B21T352N | Solution Administration Set |
| EMC9603 | 17D29T029N | Solution Administration Set |
| EMC9603 | 17G14T014N | Solution Administration Set |
| EMC9603 | 17J20T051N | Solution Administration Set |
| EMC9603 | 18C15T769N | Solution Administration Set |
| EMC9612 | 18H15T377 | Solution or Blood Administration Set |
| EMC9603 | 18A24T086N | Solution Administration Set |
| XMC4284 | 16F07T668 | PD 3L Empty Bag System II |
| XMC4284 | 16F11T734 | PD 3L Empty Bag System II |
| XMC4284 | 16F17T740 | PD 3L Empty Bag System II |
| XMC4284 | 16G15T015 | PD 3L Empty Bag System II |
| XMC4284 | 16G16T016 | PD 3L Empty Bag System II |
| XMC4284 | 16G17T017 | PD 3L Empty Bag System II |
| XMC4284 | 16G18T018 | PD 3L Empty Bag System II |
| XMC4284 | 16G19T081 | PD 3L Empty Bag System II |
| XMC4284 | 16H13T390 | PD 3L Empty Bag System II |
| XMC4284 | 16H19T396 | PD 3L Empty Bag System II |
| XMC4284 | 16I07T698 | PD 3L Empty Bag System II |
| XMC4284 | 16I08T699 | PD 3L Empty Bag System II |
| XMC4284 | 16I09T700 | PD 3L Empty Bag System II |
| XMC4284 | 16I10T701 | PD 3L Empty Bag System II |
| XMC4284 | 16I11T702 | PD 3L Empty Bag System II |
| XMC4284 | 16I18T746 | PD 3L Empty Bag System II |
| XMC4284 | 16J12T043 | PD 3L Empty Bag System II |
| XMC4284 | 16J13T044 | PD 3L Empty Bag System II |
| XMC4284 | 16J14T045 | PD 3L Empty Bag System II |
| XMC4284 | 16J15T046 | PD 3L Empty Bag System II |
| XMC4284 | 16K03T383 | PD 3L Empty Bag System II |
| XMC4284 | 16L01T693 | PD 3L Empty Bag System II |
| XMC4284 | 16L16T758 | PD 3L Empty Bag System II |
| XMC4284 | 16L28T689 | PD 3L Empty Bag System II |
| XMC4284 | 16L29T690 | PD 3L Empty Bag System II |
| XMC4284 | 16L30T691 | PD 3L Empty Bag System II |
| XMC4284 | 16L31T692 | PD 3L Empty Bag System II |
| XMC4284 | 17A18T018 | PD 3L Empty Bag System II |
| XMC4284 | 17A19T019 | PD 3L Empty Bag System II |
| XMC4284 | 17B07T338 | PD 3L Empty Bag System II |
| XMC4284 | 17B08T339 | PD 3L Empty Bag System II |
| XMC4284 | 17B09T340 | PD 3L Empty Bag System II |
| XMC4284 | 17C26T687 | PD 3L Empty Bag System II |

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| XMC4284 | 17C27T688 | PD 3L Empty Bag System II |
| XMC4284 | 17C28T689 | PD 3L Empty Bag System II |
| XMC4284 | 17C29T690 | PD 3L Empty Bag System II |
| XMC4284 | 17C30T691 | PD 3L Empty Bag System II |
| XMC4284 | 17C31T692 | PD 3L Empty Bag System II |
| XMC4284 | 17D11T041 | PD 3L Empty Bag System II |
| XMC4284 | 17D12T042 | PD 3L Empty Bag System II |
| XMC4284 | 17D13T043 | PD 3L Empty Bag System II |
| XMC4284 | 17D25T826 | PD 3L Empty Bag System II |
| XMC4284 | 17E13T375 | PD 3L Empty Bag System II |
| XMC4284 | 17E14T376 | PD 3L Empty Bag System II |
| XMC4284 | 17E15T377 | PD 3L Empty Bag System II |
| XMC4284 | 17F10T731 | PD 3L Empty Bag System II |
| XMC4284 | 17F11T732 | PD 3L Empty Bag System II |
| XMC4284 | 17F13T734 | PD 3L Empty Bag System II |
| XMC4284 | 17G01T063 | PD 3L Empty Bag System II |
| XMC4284 | 17G02T064 | PD 3L Empty Bag System II |
| XMC4284 | 17I20T681 | PD 3L Empty Bag System II |
| XMC4284 | 17J09T040 | PD 3L Empty Bag System II |
| XMC4284 | 17J15T015 | PD 3L Empty Bag System II |
| XMC4284 | 17J31T157 | PD 3L Empty Bag System II |
| XMC4284 | 17K13T434 | PD 3L Empty Bag System II |
| XMC4284 | 17K14T435 | PD 3L Empty Bag System II |
| XMC4284 | 17K18T409 | PD 3L Empty Bag System II |
| XMC4284 | 17L13T705 | PD 3L Empty Bag System II |
| XMC4284 | 17L15T707 | PD 3L Empty Bag System II |
| XMC4284 | 18A02T219 | PD 3L Empty Bag System II |
| XMC4284 | 18A05T098 | PD 3L Empty Bag System II |
| XMC4284 | 18A06T223 | PD 3L Empty Bag System II |
| XMC4284 | 18B23T494 | PD 3L Empty Bag System II |
| XMC4284 | 18C06T760 | PD 3L Empty Bag System II |
| XMC4284 | 18C08T762 | PD 3L Empty Bag System II |
| XMC4284 | 18C09T763 | PD 3L Empty Bag System II |
| XMC4284 | 18D02T002 | PD 3L Empty Bag System II |
| XMC4284 | 18D13T224 | PD 3L Empty Bag System II |
| XMC4284 | 18D18T069 | PD 3L Empty Bag System II |
| XMC4284 | 18E21T379 | PD 3L Empty Bag System II |
| XMC4284 | 18F04T717 | PD 3L Empty Bag System II |
| XMC4284 | 18F24T715 | PD 3L Empty Bag System II |
| XMC4284 | 18F26T717 | PD 3L Empty Bag System II |
| XMC4284 | 18G07T007 | PD 3L Empty Bag System II |
| XMC4284 | 18G10T010 | PD 3L Empty Bag System II |
| XMC4284 | 18G18T039 | PD 3L Empty Bag System II |
| XMC4284 | 18G21T011 | PD 3L Empty Bag System II |
| XMC4284 | 18G22T017 | PD 3L Empty Bag System II |
| XMC4284 | 18H06T426 | PD 3L Empty Bag System II |
| XMC4284 | 18H17T410 | PD 3L Empty Bag System II |
| XMC4284 | 18H27T416 | PD 3L Empty Bag System II |
| XMC4284 | 18I04T664 | PD 3L Empty Bag System II |
| XMC4284 | 18I09T722 | PD 3L Empty Bag System II |

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| XMC4284 | 18I28T741 | PD 3L Empty Bag System II |
| XMC4284 | 18J12T012 | PD 3L Empty Bag System II |
| XMC4284 | 18J12T151 | PD 3L Empty Bag System II |
| XMC4284 | 19C18T702 | PD 3L Empty Bag System II |
| XMC4284 | 20A20T180 | PD 3L Empty Bag System II |
| XMC4284 | 20A21T181 | PD 3L Empty Bag System II |
| XMC4284 | 20A22T182 | PD 3L Empty Bag System II |
| XMC4284 | 17L12T704 | PD 3L Empty Bag System II |
| XMC4284 | 18A06T099 | PD 3L Empty Bag System II |
| XMC4284 | 18A07T100 | PD 3L Empty Bag System II |
| XMC4284 | 18A08T225 | PD 3L Empty Bag System II |
| XMC4284 | 18B07T506 | PD 3L Empty Bag System II |
| XMC4284 | 18D19T109 | PD 3L Empty Bag System II |
| XMC4284 | 19L07T868 | PD 3L Empty Bag System II |
| XMC4284 | 20L03T757 | PD 3L Empty Bag System II |
| XMC4284 | 19C05T728 | PD 3L Empty Bag System II |
| XMC4284 | 19C08T731 | PD 3L Empty Bag System II |