



May 18, 2021

## **Urgent Field Safety Notice**

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

Dear Healthcare provider,

Problem Baxter Healthcare was informed by one of our third-party sterilization providers Description 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 1. Locate and remove all affected product from your facility. The product taken bv code and lot number can be found on the individual product and **Customers** 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	16107T698	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     17F13T734     PD 3L Empty Bag System II       XMC4284     17G01T063     PD 3L Empty Bag System II       XMC4284     17G02T064     PD 3L Empty Bag System II       XMC4284     17J007040     PD 3L Empty Bag System II       XMC4284     17J15T015     PD 3L Empty Bag System II       XMC4284     17J13T157     PD 3L Empty Bag System II       XMC4284     17X13T1434     PD 3L Empty Bag System II       XMC4284     17K13T434     PD 3L Empty Bag System II       XMC4284     17K13T434     PD 3L Empty Bag System II       XMC4284     17K13T435     PD 3L Empty Bag System II       XMC4284     17K13T705     PD 3L Empty Bag System II       XMC4284     17L15T707     PD 3L Empty Bag System II       XMC4284     18A02T219     PD 3L Empty Bag System II       XMC4284     18A02T23     PD 3L Empty Bag System II       XMC4284     18A02T23     PD 3L Empty Bag System II       XMC4284     18C06T760     PD 3L Empty Bag System II       XMC4284     18C08T762     PD 3L Empty Bag System II       XMC4284     18D02T002     PD 3L Empty Bag System II			
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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     17K13T435     PD 3L Empty Bag System II       XMC4284     17K13T705     PD 3L Empty Bag System II       XMC4284     17L13T705     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     18C06T760     PD 3L Empty Bag System II       XMC4284     18C06T763     PD 3L Empty Bag System II       XMC4284     18C08T762     PD 3L Empty Bag System II       XMC4284     18D02T002     PD 3L Empty Bag System II       XMC4284     18D13T224     PD 3L Empty Bag System II       XMC4284     18E21T379     PD 3L Empty Bag System II			
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