

**PRODUCT**

**RECALL**

October, 2021

**Urgent Field Safety Notice**

**Baxter Medication Delivery, Nutrition, and Renal Care Products – Third-Party Sterilization Report Falsification**

Dear Customer,

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| **Problem Description** | Baxter Healthcare was informed about a series of deviations and the manipulation of documentation which occurred at the provider of sterilization services, Steril Milano SRL. These deviations are related to the parameters and processes defined for Ethylene Oxide sterilization.Baxter has used the sterilization services of Steril Milano for the sterilization of certain lots of Medication Delivery, Nutrition, and Renal Care products. Although an internal Baxter analysis determined that sterility of the product lots listed in Annex 1 was not impacted by the documentation issue, out of an abundance of caution and in collaboration with BfArM, the coordinating competent authority, Baxter is recalling all remaining lots of product sterilized by Steril Milano from EU member states. |
| **Action to be taken by Customers** | Baxter is kindly asking that you take the following actions: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 to order replacement product.
3. Contact Baxter Healthcare Customer Service to arrange for return of the products and credit. Please have your ship-to account number ready when calling.
4. Complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it or scanning and e-mailing it or sending it by post, 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 purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier per their instructions.
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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.
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The national regulatory authority is informed about this product recall.

If you have additional questions, please contact your Baxter sales representative.

Kind regards,

Baxter Healthcare

Enclosure: Annex 1: Affected Product Table

Baxter Customer Reply Form

Home Patient Customer Letter