

## Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

| Device Details         |   |
|------------------------|---|
| Device Name            | PD 3L EMPTY Bag System & CAPD Pediatric set   |
| Device Model           | EMC9603, XMC4284, JMC3437   |
| Lot No.                | 16F27T688N / 16J22T078N / 17G14T014N / 17C31T692 / 17D25T826 / 17E15T377 / 18E21T379 / 18F24T715 / 17I15T797 / 16L01T693 / 16L28T689  |
| Manufacturer           | Baxter Healthcare   |
| Country of Origin      | Belgium   |
| Reference              | <a href="https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75917r-eng.php">https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75917r-eng.php</a>   |
| Reason of Recall       | NHRA initiates this FSN due to that certain lots of Medication Delivery and Renal Care products may not have been properly sterilized, or adequate documentation of sterilization was not provided to Baxter.               |
| Action should be taken | Please stop using the above mentioned medical device and contact the authorized representative Gulf Pharmacy at <a href="mailto:quality@gctbahrain.com">quality@gctbahrain.com</a> to take the necessary action for recall. |

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact [Medical\\_Devices@nhra.bh](mailto:Medical_Devices@nhra.bh)