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	Infusion Sets for Alaris™ Pump
Device Model	GP, VP, CC, GW/GW800, SE, IVAC 590 series
Lot No.	E105-2000E7D / E105-60693E / E105-G30402M / E105-72503E / E105-60643E / E105-60393E / E105-4301433200 / E105-G40020B
Manufacturer	Becton Dickinson
Country of Origin	Bosnia
Reference	https://www.bd.com/a/90100
Reason of Recall	NHRA initiates this FSN due to falsified sterilization process by 3rd party sterilization services provider. The manufacturer is unable to guarantee the sterility of the devices listed above which may affect patient safety.
Action should be taken	The use of non-sterile devices in the clinical setting could lead to an increased risk of infection which may cause serious harm or life-threatening conditions. Please stop using the above mentioned medical devices and contact the authorized representative YMH at me.regulatory@ymh.com.bh 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

Recall 2021 0017