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	BD OneFlow™	
Affected Device	**Serial No**	**Lot No**
	658619	1071401 , 1160783 , 1180261 , 1258383
	659912	1266231 , 1316879
Manufacturer	BD	
Country of Origin	Switzerland	
Reference	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16141	
Reason of Alert	NHRA initiates this FSN due to the manufacturer has determined through internal investigation that a common material lot used to manufacture the affected products has an uncharacteristic profile exhibited by an extra peak in a flow histogram that has been confirmed to be caused by CD8 contamination.	
Action should be taken	Please stop the above mentioned product and contact the authorized representative Wael Pharmacy at vincent@waelpharmacy.com 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 2022 0024