


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 BBL™ Gram Stain Kit
Device Model	212539
Lot No.	0014322 / 0041114
Manufacturer	BD
Country of Origin	Switzerland
Reference	https://www.bd.com/en-us/support/recall-notifications/recall-notification-bd-bbl-gram-crystal-violet-250ml-gram-crystal-violet-3-8l-and-grain-stain-kit
Device picture	
Reason of Recall	NHRA initiates this FSN due to potential to exhibit increased levels of artifacts which could be difficult to distinguish from gram positive cocci. Use of products with increased levels of artifacts could result in a false-positive Gram stain. Gram stain results must be confirmed with additional procedures, but if these protocols are not followed, a false-positive could lead to administration of unnecessary antibiotics or surgical procedures.
Action should be taken	Please stop using the above-mentioned defected product and contact the authorized representative Wael Pharmacy at vincent@waelpharmacy.com to take the necessary action for recalling the product

For more information please contact Medical_Devices@nhra.bh