


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	Chloraprep 3ml applicator
Device Model	260400 & 260415
Lot No.	802991, 8044761, 8074922, 8025597 & 8055949
Manufacturer	Becton Dickinson
Country of Origin	Switzerland
Reference	https://www.bd.com/assets/documents/alerts/MDS_BD-Chloraprep-3mL-recall-062020_CL_EN.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to storage condition of the ChloraPrep 3 mL consistently at 30°C / 75%RH for more than six months causes the growth of Aspergillus penicillioides resulting in a breach in the package integrity.
Action should be taken	Please stop using the above defected medical device 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