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	Skin Preparation Electrode gel
Device Name	LemonPrep PediaPrep, WavePrep and CardioPrep
Lot No.	All
Manufacturer	Mavidon Medical
Country of Origin	USA
Reference	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/mavidon-issues-voluntary-worldwide-recall-manufactured-products-including-lemonprepr-tubes-and
Device picture	
Reason of Recall	NHRA initiates this FSN due to that mentioned products maybe contaminated with microorganism Burkholderia cepacian leading to an infection risk to the patients.
Action should be taken	Stop using all lots of the above defected medical devices and contact your Authorized Representative to take the necessary action for withdrawal procedures.

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

For more information please contact Medical_Devices@nhra.bh