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	In-Ka® ureteral balloon dilatation catheter kit
Device Model	BD4144 BD4145 BD4146
Lot No.	attached
Manufacturer	Coloplast A/S
Country of Origin	Denmark
Reference	https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=10803
Reason of Recall	NHRA initiates this FSN due to the expiration date labelled on the IN-KA® Ureteral balloon dilatation catheter kit is not correct. The shelf life of one component within the kit (syringe) is shorter than the expiration date of the kit.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Behzad Medical Est at Imran@behzadmedical.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 2022 0044