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	Prismaflex TPE2000 Set
Device Model	107144
Lot No.	20B2325M
Manufacturer	Baxter
Country of Origin	Italy
Reference	https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=9335
Reason of Recall	NHRA initiates this FSN due to inaccurate and/or false documentation related to the sterilization processes provided by a third party contract supplier **"Steril Milano".** These deviations are related to the parameters and processes defined for Ethylene Oxide sterilization.
Action should be taken	Please stop using the above mentioned defected medical device and contact the authorized representative YMH at me.regulatory@ymh.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 2021 0057