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	Covidien Dar airway products
Device Model	20K0505FAX - 20K0501FAX - 20J1385FAX - 20J1384FAX - 20J1295FAX - 20J1294FAX - 20J1293FAX - 20J0836FAX - 20J0835FAX - 20H0631FAX - 20G1531FAX - 20D1402FAX - 20C1162FAX - 20C1159FAX 20A0107FAX - 20A0106FAX - 19K0500FAX - 19J0402FAX - 19H0122FAX - 19G1299FAX - 19G1099FAX 19G0917FAX - 19G0659FAX - 19B0388FAX - 18M0761FAX - 18M0760FAX - 18K0604FAX - 18K0358FAX 18K0357FAX
Manufacturer	Medtronic
Reference	https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75575r-eng.php
Reason of Recall	NHRA initiates this FSN due to of potential deviations from validated parameters for ethylene oxide sterilization. The deviations affect certain production lots of Medtronic's Covidien DAR™ airway products and occurred between March 2018 and February 2021.
Action should be taken	Please stop using the above mentioned medical devices and contact the authorized representative **Behzad Medical** at lijo.joy@behzad.medical.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 0027