

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 | EMG TUBE 8229707 NIM TRIVANTAGE™ 7.0MM ID |
| Device Model | 8229707 |
| Lot No. | 0225849141 |
| Manufacturer | MEDTRONIC |
| Country of Origin | USA |
| Reference | https://laegemiddelstyrelsen.dk/da/nyheder/senest-opdaterede-indhold/~media/C087A1469BAC4F0788832D3F5042BEB8.ashx |
| Reason of Recall | NHRA initiates this FSN due to reports received by the manufacturer from customers experiencing noise from the NIM system, lead-off or high impedance issues, or loss of/intermittent nerve monitoring. The potential hazards can cause unintended extubation, a delay or a cancelation of the case or dysphonia, dysphagia, dyspnea, or possible nerve damage> |
| Action should be taken | Please stop using the above mentioned medical device and contact the authorized representative BEHZAD MEDICAL EST. W.L.L at info@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