

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	HLS & PLS set
Device Model	BE-HLS 7050 Set Advanced 7.0
Ref No.	701069073
Manufacturer	GETINGE
Country of Origin	SWEDAN
Reference	https://mhra.gov.filecamp.com/s/tlrfpjsRIN0bxfHs/d
Reason of Recall	NHRA initiates this FSN due to the Potentially compromised sterile barrier. Exposure to a non-sterile or potentially non-sterile medical device, or a delay in the procedure, may result in following immediate and/ or long-range health consequences: - Inflammation, Infection, Sepsis, - Ischemia - User Inconvenience
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for technology at quality@gctbahrain.com 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