



## **Medical Devices Safety Notice**

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors to stop importing and using following medical device:

Device Details			
<b>Device Name</b>	CleanLine –Ultra Sound-Gel Sanitizer		
Manufacturer	LAL Chemicals & Cosmetics	Country of Origin	KSA
Source/ reference	https://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx		
Device picture	CLEAN LINE — ULTRA SOUNDS  Sanitize  250 m  The standard control of the standa		
Reason of Recall	After examining 3 samples of the above product, it was found that the product did not comply with the standard (ANSI / AAMI / ISO 10993-5) where the percentage of <b>cytotoxicity</b> was found to be very high (4 by scale from 0 to 4) and not suitable for medical use		
Action required	In case of having the defected device in your stock, please stop using it for users and patient's safety.		

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.