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	GELITA TUFT-IT® GELITA-SPON® RAPID³ GELITA-SPON® STANDAR
Device Model	GF-7365 GR-010 GS-210
Lot No.	F00076/1 R00111/2 T02407/3
Manufacturer	GELITA MEDICAL GmbH
Country of Origin	Germany
Reference	https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=10755
Reason of Recall	NHRA initiates this FSN due to the endotoxin concentration of the product in some samples has been measured above the limit.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative innovation medical equipment at innovation@innovation-me.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

Recall 2022 0041