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	Remel Rapid™ NF System
Device Model	R8311005
Lot No.	3364798 3364799 3364800 3381406 3390383 3442256 3442431
Manufacturer	ThermoFisher
Country of Origin	UK
Reference	https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-01040-1
Reason of Recall	NHRA initiates this FSN due to a technical investigation has determined ATCC 19606 (Acinetobacter baumannii ATCC® 19606), ATCC 13253 (Elizabethkingia menigoseptica ATCC® 13253) and blank (NF reagent) gave a positive reaction where it should have given a negative reaction within the NO3 well of the panel.
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.

For more information please contact Medical_Devices@nhra.bh

Recall 2022 0040

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

For more information please contact Medical_Devices@nhra.bh