



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	Histocore Arcadia H
Device Model	1102
Lot No.	1102
Manufacturer	Leica Biosystem
Country of Origin	Germany
Reference	Link
Reason of Recall	NHRA initiates this FSN due to the deformation of the device paraffin tank, which can tear the seal and cause paraffin leaks. This may lead to toxic smoke and internal fires due to compromised insulation material.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Global Consultancy House at <u>ahmeds@gchservice.com</u> 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