

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	Hemospray Endoscopic Hemostat
Device Model	HEMO-7-EU
Lot No.	W3915373-3, W3991856-1, W4163471-6, W4163796-10, W4049196-1
Manufacturer	Cook Medical
Country of Origin	Germany
Reference	https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72371r-eng.php
Reason of Recall	NHRA initiates this FSN due to cracking or breaking in the handle and/or activation knob while the device is activated, prior to and during use and this has led to the carbon dioxide cartridge exiting the handle.
Action should be taken	Please stop using the above-mentioned defected device and contact the authorized representative YMY at me.regulatory@ymh.com.bh 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