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	MAQUET (VHK and VKMO(D) Adult/Small Adult Accessories)
Device Model	Please refer to the reference link below
Manufacturer	MAQUET Cardiopulmonary GmbH
Country of Origin	Germany
Reference	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14873
Device picture	
Reason of Recall	NHRA initiates this FSN due to a potential impairment of the sterile packaging of the accessories was detected during the verification test of **Adult/Small Adult VKMOs and VHK** that were manufactured after 4th March 2019, excessive movement of the device and its accessories in the carton can lead to stress points that could compromise the sterile barrier of the packaging of the device.
Action should be taken	In case of having the above defected medical device, please stop using it and contact your local agent to take the necessary action for replacement.

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

For more information please contact Medical_Devices@nhra.bh