Medical Device Sector Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

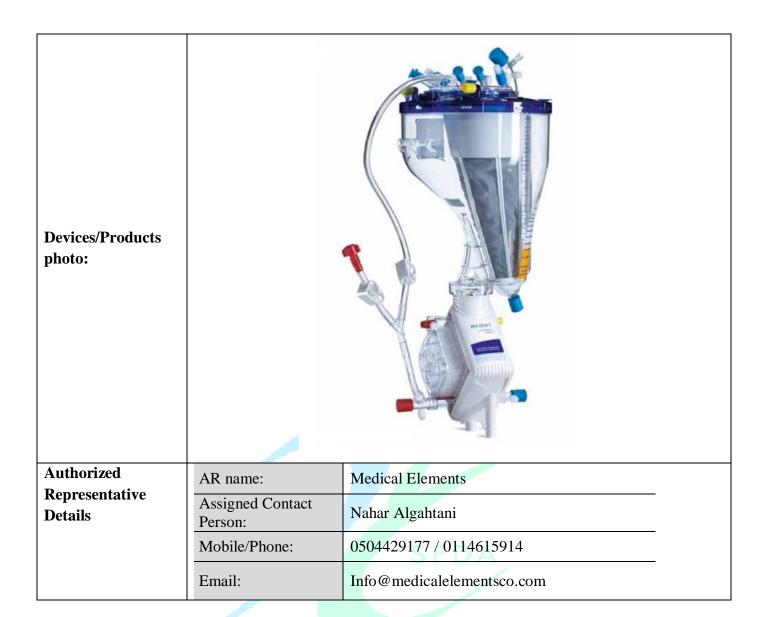
Safety Communication

رسالة سلامة

VHK and VKMO(D) Adult/Small Adult Accessories - Sterile Barrier Integrity

Device/ Product	
	VHK and VKMO(D) Adult/Small Adult Accessories
Description:	
Brand Name:	MAQUET
Lot numbers/Serials:	 701067941 - VKMO 78000 #SQUADROX-i HMO 70000+VHK7000 701067942 - VKMO 70000 #SQUADROX-i HMO 70000+VHK71000 701067948 - BO-VKMO 70000 #SQUADR-i HMO70000+VHK71000 701067949 - VKMO 71000 #SQUADROX-i HMO 71000+VHK71000 701067951 - BO-VKMO 71000 #SQUADR-i HMO71000+VHK71000 701067956 - BE-VKMO 70000 #SQUADR-i HMO70000+VHK71000 701067962 - BO-VKMOD 71000 #SQUADROX-iD 71000+VHK71000 701067968 - VKMO 50000 #SQUADROX-i HMO 50000+VHK71000 701067969 - VKMO 51000 #SQUADROX-i HMO50000+VHK71000 701063859 - BE-VHK 71000#Venöses Reservoir VHK 71000 701062605 - VHK 71000#Venöses Reservoir VHK 71000
Manufacturer:	MAQUET Cardiopulmonary GmbH
Problem:	During verification testing of Adult/Small Adult VKMOs and VHK a potential impairment of the sterile packaging pouches of the accessories was detected for products manufactured after the 4th of March 2019. Under unfavorable transport conditions, 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 pouches. Exposure to a non-sterile or potentially non-sterile medical device may result in infection-causing inflammatory like syndromes thereby deteriorating the clinical state of the patient. Additionally, infection may occur if the device is connected to the central circulatory system.
Recommendation/ Actions:	 Remove and do not use the accessories, 3-way manifold line, Tight caps and Adapter for recirculation line In case you do not want to use this product without the accessories, please return the product to your local authorized representative.

SG-1910-116-H 01/10/2019



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