Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

| **Safety Communication** | **رسالة سلامة** |

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

Device/ Product Description:	VHK and VKMO(D) Adult/Small Adult Accessories
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 • 701067966 - VKMO 50000 #SQUADROX-i HMO 50000+VHK71000 • 701067968 - BO-VKMO 50000 #SQUADR-i HMO50000+VHK71000 • 701067969 - VKMO 51000 #SQUADROX-i HMO 51000+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.

Devices/Products photo:		
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