

Circular No. 14 / 2022

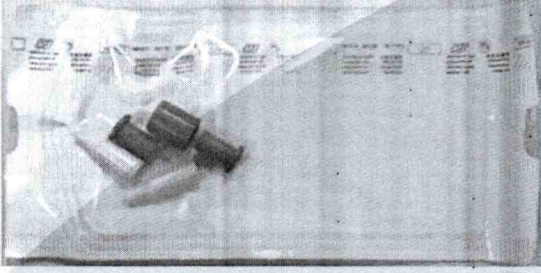
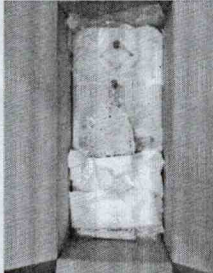
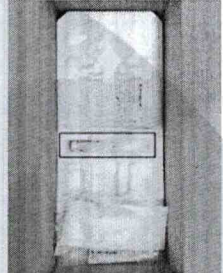
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24 -01-2022

ببمقدار ثقة  
Moving Forward  
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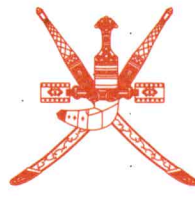
رؤية عمان  
2040  
Oman Vision

**Recall of VHK and VKMO Neonatal from Maquet Cardiopulmonary GmbH.**

Source	GHC-Gulf Health Council			
Product	<ul style="list-style-type: none"> <li>Combination of Neonatal Venous Hardshell Cardiotomy Reservoir with QUADROX-I Neonatal Oxygenator with or without coating.</li> <li>Combination of Pediatric Venous Hardshell Cardiotomy Reservoir with QUADROX-I Pediatric Oxygenator.</li> <li>Pediatric Venous Hardshell Cardiotomy Reservoir.</li> <li>Neonatal Venous Hardshell Cardiotomy Reservoir.</li> </ul>			
Manufacturer	Maquet Cardiopulmonary GmbH.			
Local Agent	Mustafa Sultan Science & Industry.			
The affected products	<b>Navigation System</b>	<b>Software Name</b>	<b>Model#/CFN</b>	<b>Version</b>
	StealthStation S7/i7	Synergy Cranial S7	9733763	2.2.8
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.1
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.2
	StealthStation S7/i7	StealthStation Cranial	9735585	3.1.3
Reason	A potential impairment of the sterile package of the system and the accessory part "tight caps".			
Action	<ol style="list-style-type: none"> <li>Please quarantine and return immediately all affected products.</li> <li>Contact the local agent for remedial action.</li> </ol>			
Product Picture	  			
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>			

*ASD*  
/ Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL





تقدم بثقة  
Moving Forward  
with Confidence

رؤية عمان  
2040  
Vision

To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**

**Commanding Officer, Armed Forces Hospital (Al Khouth & Salalah)**

**Director General of Engineering Affairs, MOH**

**Director General of Royal Hospital**

**Director General of Khoula Hospital**

**Director General of Medical Supplies (MOH)**

**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**

**Hospital Director (Al Nahda Hospital)**

**Hospital Director (Al Massara Hospital)**

**The Head of Medical Services in SQU Hospital**

**The Head of Medical Services in Royal Oman Police**

**The Head of Medical Services in Ministry of Defence**

**The Head of Medical Services in The Diwan**

**The Head of Medical Services in The Sultan's Special Force**

**The Head of Medical Services in Internal Security Services**

**The Head of Medical Services in Petroleum Development of Oman**

**The Head of Medical Services in LNG Oman**

**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No. *14/2022*, dated *24/1/2022* Regarding GHC recall of VHK and VKMO Neonatal from ( mrf: Maquet Cardiopulmonary GmbH).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





تقارير السلامة للأجهزة والمستلزمات الطبية  
Safety Alerts of Medical Device Products

<b>To:</b> HE / Members of the Executive Committee of the Cooperation Council States Members		<b>إلى:</b> سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.		
<b>Subject:</b>	تحذير سلامة لعدد (4) منتجات طبية من إنتاج شركة (Maquet Cardiopulmonary GmbH)			
<b>Product Name:</b>	<ul style="list-style-type: none"><li>Combination of Neonatal Venous Hardshell Cardiomy Reservoir with QUADROX-I Neonatal Oxygenator with or without coating.</li><li>Combination of Pediatric Venous Hardshell Cardiomy Reservoir with QUADROX-I Pediatric Oxygenator.</li><li>Pediatric Venous Hardshell Cardiomy Reservoir.</li><li>Neonatal Venous Hardshell Cardiomy Reservoir.</li></ul>			
<b>Company:</b>	Maquet Cardiopulmonary GmbH			
<b>Affected product:</b>	<b>Reference Numbers:</b>	<b>المنتجات المتأثرة:</b>		
	VHK 11000	BO-VHK 11000	BO-VHK 11000-J	VKMO 11000
	VKMO 10000	BO-VKMO 11000	BO-VKMO 10000	BO-VKMO 31000
	VKMO 10000	VKMO 31000	BO-VKMO 11000	BO-VHK 31000-J
	VKMO 11000	VHK 31000	BO-VKMO 11000 -J	VKMO 30000
	VKMO 30000	BO-VHK 31000	BO-VKMO 30000	
<b>Reg. Status in GHC:</b>	Not registered			<b>وضع المنتج في مجلس الصحة:</b>
<b>Source of Warning:</b>	SFDA			<b>مصدر التحذير:</b>
<b>Reason for Warning:</b>	SFDA status that there is A potential impairment of the sterile package of the system and the accessory part "tight caps".			<b>سبب التحذير:</b>
<b>Recommendation:</b>	SFDA recommended noted that "Please quarantine and return immediately all affected products".			<b>التوصيات:</b>
<b>Authorized Representative:</b>	<b>AR name:</b>	Medical Elements Co		<b>الشخص الممثل:</b>
	<b>Assigned Contact Person:</b>	Wassem Sameer Alssorani		
	<b>Mobile/Phone:</b>	+(966) 568539553		
	<b>Email:</b>	<a href="mailto:m.ilyas@medicalelementscs.com">m.ilyas@medicalelementscs.com</a>		
<b>Link of Circular</b>	For more information, please click <a href="#">here</a> & <a href="#">here</a> .			<b>رابط التعميم:</b>
<b>For inquiries and reporting:</b>	<a href="mailto:pms@ghc.sa">pms@ghc.sa</a>			<b>للاستفسارات والإبلاغ:</b>