

Safety Communication

رسالة سلامة

A potential impairment of the sterile package

Device/ Product Description:	<ul style="list-style-type: none"> Combination of Neonatal Venous Hardshell Cardiotomy Reservoir with QUADROX-I Neonatal Oxygenator with or without coating. Combination of Pediatric Venous Hardshell Cardiotomy Reservoir with QUADROX-I Pediatric Oxygenator. Pediatric Venous Hardshell Cardiotomy Reservoir. Neonatal Venous Hardshell Cardiotomy Reservoir. 																				
Affected product:	<p>Reference Numbers:</p> <table border="1" data-bbox="433 1129 1523 1297"> <tr> <td>VHK 11000</td> <td>BO-VHK 11000</td> <td>BO-VHK 11000-J</td> <td>VKMO 10000</td> </tr> <tr> <td>BO-VKMO 10000</td> <td>VKMO 11000</td> <td>BO-VKMO 11000</td> <td>BO-VKMO 11000 -J</td> </tr> <tr> <td>VKMO 10000</td> <td>VKMO 11000</td> <td>BO-VKMO 11000</td> <td>VKMO 30000</td> </tr> <tr> <td>BO-VKMO 30000</td> <td>VKMO 31000</td> <td>BO-VKMO 31000</td> <td>VHK 31000</td> </tr> <tr> <td>BO-VHK 31000</td> <td>BO-VHK 31000-J</td> <td>VKMO 30000</td> <td></td> </tr> </table>	VHK 11000	BO-VHK 11000	BO-VHK 11000-J	VKMO 10000	BO-VKMO 10000	VKMO 11000	BO-VKMO 11000	BO-VKMO 11000 -J	VKMO 10000	VKMO 11000	BO-VKMO 11000	VKMO 30000	BO-VKMO 30000	VKMO 31000	BO-VKMO 31000	VHK 31000	BO-VHK 31000	BO-VHK 31000-J	VKMO 30000	
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Manufacturer:	<p>Maquet Cardiopulmonary GmbH</p>																				
Problem:	<p>A potential impairment of the sterile package of the system and the accessory part “tight caps”.</p>																				
Recommendation /Actions:	<p>Please quarantine and return immediately all affected products.</p> <p>For more information, please click here & here.</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>																				

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