



Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Infection - Late delivery of Blood Solution

Device/ Product Description:	Volumed Transfusion Set, Non-Vented, DEHP-Free PVC, 235cm, Robson Clamp and Male Luer Lock. Sterile Item for Single Use		
Device Model:	Volumed® Set		
Affected products:	Catalogue:	APTPK0J	
	Batch:	19PH427	
Manufacturer:	Phoenix s.r.l		
Problem:	Disconnection between drip chamber and tubing which may cause Possible Infection and/or late delivery of blood solution.		
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Identify and quarantine any affected products Contact the authorized representative for the required support. For more information please click here . 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		

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