



Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Sterility of the devices cannot be guaranteed

Device/ Product Description:	Infusion Sets for Alaris Pumps (GP, VP, CC and SE) & Non-Dedicated Infusion sets and accessories		
Affected Lot Number:	Check the affected lot number in the original FIELD SAFETY NOTICE		
Manufacturer:	BD		
Problem:	The manufacturer is unable to guarantee the sterility of the devices. The use of non-sterile devices in the clinical setting could lead to an increased risk of infection which may cause serious harm or life-threatening conditions.		
Recommendation /Actions:	 Check stock for affected products and Cease use of all impacted lot numbers in your possession Make sure that this document is reached to the end-users. Follow instructions provided by the manufacturer in the FSN. Contact the authorized representative for 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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Devices/Products photo:		De la constant de la
Authorized Representative Details	AR name:	Becton Dickinson BV Saudi Limited Company
	Assigned Contact Person:	Nawaf Alsalmi
	Mobile/Phone:	+(966) 566898822
	Email:	Nawaf.M.Al.Salmie@bd.com

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