

Medical Devices Sector Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Risk of Bacteria Contamination

Device/ Product Description:	Ultrasound Gels and Lotions	
Affected product:	Multiple pack and bottle sizes, check below for complete information	
Manufacturer:	DJO, LCC. (The physical manufacturer of this product is Eco-Med Pharmaceutical)	
Problem:	Risk of bacterial contamination with Burkholderia cepacia complex (Bcc). The use of affected ultrasound gels and lotions contaminated with Bcc may lead to serious infections, including bloodstream infections, which may result in sepsis or death.	
Recommendation /Actions:	 Make sure that this document is reached to the end-users. Ensure that all devices affected are identified. Immediately stop using and discard all affected ultrasound gel and lotion. Contact the authorized representative for required support. For more information, please click <u>here.</u> If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: <u>NCMIDR</u> <u>Vigilance system</u> (19999) unified call center	
Authorized Representative Details	AR name:	Care Techniques Est.
	Assigned Contact Person:	Faisal Al-Haitty
	Mobile/Phone:	+(966) 563529920
	Email:	ct.sfda.saber@gmail.com