

Safety Communication

رسالة سلامة

The mouth wash (M Care) contains a high enumeration of bacteria and fungi

Device/ Product Description:	Damad-set Dressing pack; Oral Care Kit	
Affected product:	Reference number:	228022/1.
	Lot Number:	All
Manufacturer:	The National Medical Products Co. Ltd. (Damad)	
Problem:	The mouth wash (M Care) contains high enumeration of bacteria and fungi that exceeded the maximum allowed in addition to containing bacteria (Burkholdria cepacia complex). This may result in oral cavity infection and may develop Respiratory infection of the patient.	
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document is reached to the end-users. • Ensure that all Products affected are identified. • Stop using the Damad-set Oral Care Set. • Coordinate to withdraw the remaining quantities of the product. • Communicate in this regard through the contact details below. <p>For more information, please click 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>	

Authorized Representative Details	AR name:	The National Medical Products Co Ltd (Damad)
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