

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

## **Safety Communication**

رسالة سلامة

## Non-Compliance with the Standards

Device/ Product Description:	Examination Gloves					
Brand Name:	Secure Vinyl Examination Gloves Powder Free Non- Sterile	Secure Vinyl Examination Gloves Powder Free Non-Sterile	Secure Vinyl Examination Gloves Powder Free Non-Sterile	Medik Prime Natural Latex Examination Gloves	Medik Prime Natural Latex Examination Gloves	Medik Prime Natural Latex Examination Gloves
Affected Lot Number:	18010163	20062562	20062561	19104101	20010502	20051903
Manufacturer:	Salalah Medical Supplies Mfg. Co. LLC					
Problem:	A specific technical tastings showed Non-conformity of the mentioned medical gloves to number of technical standards. The products may not guarantee adequate insulation due to the presence of holes in the gloves.					
Recommendation /Actions:	<ul> <li>Make sure that this document is reached to the end-users.</li> <li>Identify the affected product and stop using it in a medical procedures.</li> <li>Contact the authorized representative for the required corrective action.</li> </ul> If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: <ul> <li>NCMDR</li> <li>Vigilance system</li> <li>(19999) unified call center</li> </ul>					

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