

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

## **Safety Communication**

رسالة سلامة

## Manufacturer Warns of Increased Risk of Fake Counterfeit Product

Device/ Product Description:	Healthcare Particulate Respirator and Surgical Masks		
Problem Summary:	SFDA has dealt with reports of fraud 3M N95 respirator and surgical masks that have included fake/counterfeit products. Moreover, Emergency Care Research Institute (ECRI) has published international alert related to this issue based on 3M alert.		
Recommendation /Action:	<ul> <li>Make sure that this document, with accompanying alert is reached to the endusers.</li> <li>Contact the authorized representative with any questions or concerns.</li> <li>Purchase the respirators through authorized distributors.</li> <li>For more information, please click here.</li> </ul>		
Affected Product:	Product	Model No.	Lot No.
	Healthcare Particulate Respirator and Surgical Masks	1860	B19029, B19206, B19240, B19130, B19133, B19155, B19161, B19206, B19314, B20010, B20013, B20016, B20018, B20020, B20021, B20022, B20025, B20060, B20119, B20245, R20025, R20102, R20144, R20150, R20294
		1860S	B20522, B20659, B20670, R20522
	Aura Healthcare Particulate Respirator and Surgical Masks	1870+	C193041, C190241
	If you suspect of any other lots according the same counterfeit specifications mentioned in the manufacturer's letter, please report to SFDA through:  NCMDR  Vigilance system  19999 unified call center		

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Manufacturer:	3M Health Care		
Devices/Products Photo:	AND AND THE COMMENT OF THE COMMENT O		
	AR name:	3M Arabia	
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