

Kingdom of Saudi Arabia Saudi Food & Drug Authority



Medical Devices Sector Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقيأسات الحيوية

Safety Communication

رسالة سلامة

Use of an Isolation Transformer in combination with Sentec's Digital Monitor in home care settings

10

Device/ Product Description:	Digital Monitor	
Ref. Numbers:	SDM	
Manufacturer:	SenTec AG.	
Problem:	Non-compliance of the affected devices with normative requirements from IEC 60601-1-11:2015 Medical electrical equipment when used in home environments.	
Recommendation /Actions:	 Make sure this document is reached to the end-user Use of an isolation transformer in combination with the SDM in home care settings to comply with applicable safety standards. 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: NCMDR Vigilance system (19999) unified call center 	
Authorized Representative Details	AR name:	Medical Regulations Gate
	Assigned Contact Person:	Abdullah Alsaiari
	Mobile/Phone:	+966 540640847
	Email:	ameen@mr-gate.com