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قطاع الأجهزة والمستلزمات الطبية المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector National Center for Medical Devices Reporting الميئة الحامة للخذاء والحواء Saudi Food & Drug Authority

رسالة سلامة Safety Communication

To: Healthcare Provider	,	إلى: مقدمي الرعاية الصحية	
Title	Recommendations for Healthcare Providers regarding the safe and effective use of Autoclave Devices	العنوان	
Medical Device Description	Autoclave Devices	اسم ووصف الجهاز/المستلزم الطبي	
Manufacturer	All	اسم المصنع	
Authorized Representative	All	الممثل المعتمد	
Medical Devices Marketing Authorization (MDMA)	All	إذن التسويق	
Potential /Associated risks	According to the SFDA's survey report on autoclave devices, which was distributed to saudi healthcare providers to seek feedback on their experience with the autoclave devices. The report identified a number of possible risks and concerns. As a result, the SFDA recognized the importance of emphasizing safety recommendations to individuals who use steam sterilization devices to avoid possible risks related with autoclave usage, such as heat burns and scalds.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي	
Recommendations	 Healthcare providers must: Use autoclave devices that approved by SFDA with an MDMA certificate. Specialized, trained, and qualified to use autoclave devices by receive comprehensive training on how to operate the autoclave correctly. Follow the manufacturer's recommendations for proper installation, operation, cleaning, and maintenance. Place the user manual near the autoclave device being used. Wear personal protective equipment, such as gloves, goggles, and lab coats, when using the device. They acts as a barrier, shielding from potential hazards. Ensure the autoclave is well-ventilated to prevent moisture and heat buildup. Regularly monitor the autoclave's pressure and temperature gauges during operation. 	التوصيات	
For Reporting	SFDA 19999 NCMDR Oction line Standi Vigilance Standi Vigilance	للإبلاغ	

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