

Date: 04-Oct-2026

Reference Number: SG-2610-439-H

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector

National Center for Medical Devices Reporting

Safety Communication

رسالة سلامة

To: Healthcare Providers and Practitioners	إلى: مقدمي الرعاية الصحية والممارسين الصحيين
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Title	<i>Incorrect Public IP Configuration and Example</i>	العنوان
Medical Device Description	<i>EDAN Patient Monitoring and Fetal Monitoring Devices.</i>	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	<i>Edan Instruments Inc.</i>	اسم المصنع
Authorized Representative	<i>Medical Regulations Gate</i>	الممثل المعتمد

Medical Devices Marketing Authorization (MDMA)	MDMA-2-2026-2770	إذن التسويق
Potential /Associated risks	1. Labeling issue: An inappropriate publicly routable IP address was used as an example in the user manual for demonstrating user-configurable IP address settings. 2. Default setting issue: An inappropriate publicly routable IP address was used as the factory default configuration. Customers may be misled by the user manual or factory default IP settings, in extreme scenario, resulting in the following risk: An attacker may exploit unintended communication with an external public IP to send falsified data to the monitor, resulting in abnormal operation of the monitor and delayed treatment of patients.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	Verify that the prohibited IP address range 202.114.4.* is not configured in the device's User Maintenance settings. If it is, instruct users to update the network settings to an appropriate IP address in accordance with the Instructions for IP Settings Configuration. Healthcare providers and practitioners are highly advised to report any related incident /Adverse Event to SFDA.	التوصيات

For Reporting	 	للإبلاغ
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