

Safety Alerts Weekly Update

Report Reference: WU2553
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التقرير الأسبوعي لإنذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

below is the weekly report of Safety Alerts for the period:

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 21-Dec-25 من
To 27-Dec-25 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمتأثرة بها المملكة والتي جاري متابعتها مع الممثلين المعتمدين لإتمام تنفيذ الإجراءات التصحيحية.

*** Kindly respond to the weekly report in both cases either you are affected or not affected though the following link:**

*** نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر وذلك من خلال الرابط أدناه:**

<https://surveys.sfda.gov.sa/surveys/?s=4MT7LEJ3DFP7H8LJ>



*** Role of contact officer:**

- Disseminate and share the information with other departments within the healthcare facility and ensure that the healthcare facility is free of any affected device/product.
- Communicate with the Authorised Representative of the manufacturer if there is any device/product affected by a Safety Alert
- To identify the affected serial numbers/lots, please open the Safety link.

*** مسؤولية ضابط الاتصال:**

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إنذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إنذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إنذار السلامة:



No. of Safety Alerts: 15 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-11-12-25-1177	Zimmer Air Dermatome and Zimmer Dermatome AN	Zimmer Biomet	Zimmer Biomet Asel Alarabia	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
2	SA-21-12-25-1190	Tego™ Connector	ICU Medical, Inc	AL-KAMAL Import	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
3	SA-18-12-25-1188	basixCOMPAK Inflation Device	Merit Medical Systems Inc....	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
4	SA-17-12-25-1186	da Vinci Single Port System Access Port Kits	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
5	SA-24-12-25-1196	- CODMAN MICROSENSOR® Basic kit and - CERELINK® ICP sensor Basic kit	Integra LifeSciences Production Corporation	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
6	SA-17-12-25-1187	Philips Allura Xper and Allura CV20 Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
7	SA-19-12-25-1189	Efficia DFM100 Defibrillator/Monitor	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
8	SA-23-12-25-1192	Centricity RIS-i	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-23-12-25-1193	AXIOS™ Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
10	SA-23-12-25-1194	XN series Blood Bank mode	Sysmex Corporation	Sysmex LLC One Person Co	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
11	SA-22-12-25-1191	Patient Information Center iX	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
12	SA-24-12-25-1195	Damad-Prep Pad; Povidone-Iodine swabstick, 2 swabsticks /packet	The National Medical Products Co. Ltd. (Damad)	The National Medical Products Co. Ltd. (Damad)	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
13	SA-24-12-25-1197	Omni Legend	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
14	SA-10-12-25-1175	Asserachrom HPIA	Diagnostica Stago S.A.S.	Diagnostic Saudi Arabia Trading Company	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
15	SA-12-10-25-1089	BD Alaris Syringe Pumps	BD Switzerland Sarl	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices