



Safety Alerts Weekly Update

Report Reference:

WU2553

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28-Dec-25

التقرير الأسبوعي لإذارات السلامة

الرقم المرجعي للتقرير:

تاريخ النشر:

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

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.

فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

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 متاثر بأي من إذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متاثر بأي من إذارات السلامة.

لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتاثرة، 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 Electrosurgical 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