

Safety Alerts Weekly Update

Report Reference: WU2541
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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 28-Sep-25 من
To 04-Oct-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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-25-09-25-1066	Catalyft™ PL & PL40 expandable interbody system	Medtronic SA	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Non-active implantable devices
2	SA-25-09-25-1067	AlloSeq® cfDNA	care dx Pty Ltd...	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
3	SA-29-09-25-1072	Alinity hq Analyser	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/Publish	Laboratory equipment
4	SA-29-09-25-1071	Leksell Vantage Arc System	Elekta Inc	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/Publish	Reusable devices
5	SA-28-09-25-1068	ORTHO CONNECT	Biomedical Data Solutions Ltd.	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Laboratory equipment
6	SA-30-09-25-1075	Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
7	SA-28-09-25-1070	UniCel DxI 600 and 800 Analyzers	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
8	SA-30-09-25-1073	CARESCAPE B450, CARESCAPE ONE, B1x5M/B1x5P VSP3.0, B1x5M/B1x5P VSP4.0 Patient Monitors and Portrait Vital Signs Monitor	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/567	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-02-10-25-1076	Digital Diagnostic Mobile X-ray System GM85	Samsung Electronics..	ATTIEH MEDICO LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/281	Diagnostic and therapeutic radiation devices
10	SA-26-01-25-766	LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators	LivaNova PLC	cigalah group	https://ade.sfda.gov.sa/Fsca/PublishDetails/281	Active Implantable Devices