

Safety Alerts Weekly Update

Report Reference: WU2545
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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 26-Oct-25 من
To 01-Nov-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-28-10-25-1114	CAPI 3 IMMUNOTYPING (Product number 2600)	Sebia.	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
2	SA-24-10-25-1107	Kendall SCD 700 Sequential Compression System	Cardinal Health 200, LLC..	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
3	SA-27-10-25-1112	ErgoStar CM 40, ErgoStar CM 45, ErgoStar CM 55, ErgoStar CM 60	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Anaesthetic and respiratory devices
4	SA-24-10-25-1109	Various Clear-Therm™ Mini HMEF	Intersurgical Limited	Al Hammad Medical Services	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
5	SA-26-10-25-1110	BD Alaris System Pump (8100) & Bezel Spare Parts	CareFusion 303, Inc..	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
6	SA-28-10-25-1115	CareLink™ Clinic	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
7	SA-29-10-25-1119	NextSeq™ 550Dx sequencing reagent kits	Illumina Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
8	SA-29-10-25-1117	Aurora EV-ICD™ (DVEA3E4), Clinical EV-ICD (DVEX3E4)	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Active Implantable Devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-30-10-25-1120	Cardiosave Hybrid	Getinge	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
10	SA-28-10-25-1116	Becker and Exacta external drainage and monitoring systems (EDMS).	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices