

Safety Alerts Weekly Update

Report Reference:

WU2508

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16-Feb-25

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 **09-Feb-25**

من

To **15-Feb-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:**

*** مسؤولية ضابط الاتصال:**

- 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.

- 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: 8 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-11-02-25-783	AlinIQ AMS	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Medical software
2	SA-06-02-25-777	Aortic Root Cannula	Medtronic SA	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Single-use devices
3	SA-13-02-25-785	Centricity Universal Viewer and Centricity PACS-IW	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Medical software
4	SA-12-02-25-784	DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	In vitro diagnostic devices
5	SA-09-02-25-779	Haemostatic Forceps	Aesculap	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Reusable devices
6	SA-06-02-25-778	MiniMed™ Paradigm™, MiniMed™ 600 series, and MiniMed™ 700 series insulin pump systems	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Electro mechanical medical devices
7	SA-09-02-25-780	Olympus MAJ-891 Forceps/Irrigation Plug (Isolated Type)	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Electro mechanical medical devices
8	SA-10-02-25-782	Oral Care Set	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ade.sfda.gov.sa/Fsca/PublishDetails/286	Single-use devices