

Safety Alerts Weekly Update

التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2424

الرقم المرجعي للتقرير:

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09-Jun-24

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 02-Jun-24

من

To 08-Jun-24

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=CTLNDA7ARTRDHMA>



* 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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات 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-02-06-24-439	Access HbC Ab Reagent	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
2	SA-05-06-24-444	BD BBL Sensi-Disc	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
3	SA-28-05-24-431	Cascade IOMAX Cortical Module	Cadwell Industries Inc	Raneen med	https://ncmdr.sfda.gov.sa/Secure/CA/	Hospital hardware
4	SA-30-05-24-438	Centricity High Acuity Anesthesia (CHA A) system	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/	Anaesthetic and respiratory devices
5	SA-02-06-24-440	FlowPRA™ HLA Class I Screening Test	One Lambda Inc	Farabi Trading Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
6	SA-04-06-24-443	LIAISON® Testosterone	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
7	SA-03-06-24-441	Multiva 1.5T systems equipped with g-MDU	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	Diagnostic and therapeutic radiation devices
8	SA-21-05-24-423	Plum 360 Infusion System and Plum A+ & Plum A+3 Infusion Systems	ICU Medical, Inc	AL-KAMAL Import	https://ncmdr.sfda.gov.sa/Secure/CA/	Electro mechanical medical devices
9	SFDA-0048-2024	SMD Disposable Infusion Set	SECURED MEDICAL DIRECTION UK CO., LTD	almarar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-04-06-24-442	Vitros Chemistry Products Calibrator Kit 29	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda	In vitro diagnostic devices