

Safety Alerts Weekly Update

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التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 04-Feb-24
To 10-Feb-24

من
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=CTLNDA7ARTRDHM>



* 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 إذار السلامة:

No. of Safety Alerts: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-06-02-24-272	Access Total T4 Thyroxine Reagent	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
2	SA-02-01-24-237	Allura Xper, Allura Centron, and Azurion Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
3	SA-05-02-24-270	LIAISON® Q.S.E.T. Device Plus	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
4	SA-07-02-24-279	Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube	Medtronic XOMED, Inc	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=199	Single-use devices
5	SA-07-02-24-276	Multichem S Plus, Multichem IA Plus, Multichem P	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
6	SA-06-02-24-273	NeuMoDx™ HIV-1 Quant Test Strip	QIAGEN Ltd	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
7	SA-07-02-24-275	NextSeq 550 Dx and MiSeq Dx instruments	Illumina Inc	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
8	SA-07-02-24-277	Original Perfusor® Line	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	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
9	SA-05-02-24-271	Philips Azurion System	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
10	SA-05-02-24-269	REANIBEX 100	Osatu S.Coop.	aldawaa medical services	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
11	SA-07-02-24-274	VITROS 3600 Immunodiagnostic System□ VITROS 5600 Integrated System□ VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=199	In vitro diagnostic devices