

Safety Alerts Weekly Update

Report Reference: WU2518
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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 20-Apr-25 من
To 26-Apr-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: 15 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-20-04-25-864	Stratus® CS Acute Care™ cTnI TestPak	Siemens Healthcare Diagnostics Inc.	HIGH STANDARD MEDICAL INC	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	In vitro diagnostic devices
2	SA-21-04-25-867	Flexi Port Reusable Blood Pressure Cuffs and Two-Piece Reusable Blood Pressure Cuffs kits	Welch Allyn, Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	Reusable devices
3	SA-17-04-25-862	ParaPAC plus™ Model 300 and Model 310 Ventilator	Smiths Medical ASD, Inc.	almadar medical Est.	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	Electro mechanical medical devices
4	SA-15-04-25-857	AU/DxC AU Creatinine	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	In vitro diagnostic devices
5	SA-20-04-25-866	Access Erythropoietin (EPO)	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	In vitro diagnostic devices
6	SA-20-04-25-865	AU480 and AU680 Clinical Chemistry Analyzers	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	In vitro diagnostic devices
7	SA-16-04-25-858	Tempus Pro Monitor	Remote Diagnostic Technologies Ltd..	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	Electro mechanical medical devices
8	SA-18-04-25-863	Tempus Pro Monitor	Remote Diagnostic Technologies Ltd..	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/368	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-17-04-25-861	Xpert® BCR-ABL Ultra P190	Cepheid...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
10	SA-22-04-25-869	Apolipoprotein (Apo) B Reagent	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
11	SA-22-04-25-868	HKH 8820 Wall Holder	MAQUET Cardiovascular LLC.	Medical Elements	https://ade.sfda.gov.sa/Fsca/PublishD	Hospital hardware
12	SA-17-03-25-817	Atellica CH Revised C-Reactive Protein (RCRP)	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov	In vitro diagnostic devices
13	SA-26-07-24-532	FREEGO ENTERAL FEEDING PUMP	Zevex International Inc	Abbott Saudi Arabia for Trading	https://ade.sfda.gov	Electro mechanical medical devices
14	SA-08-01-24-242	MR systems with 60cm wide bore	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
15	SA-02-12-24-694	<ul style="list-style-type: none"> - Tec 6 Plus - Tec 820 ISO - Tec 820 SEV - Tec 850 ISO - Tec 850 SEV 	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/205	Anaesthetic and respiratory devices