

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2527
Publish date: 29-Jun-25

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 22-Jun-25
To 28-Jun-25

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=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: 8 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-25-06-25-938	Medtronic CareLink™ SmartSync™ Device Manager (SmartSync)	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	Active Implantable Devices
2	SA-24-06-25-936	- UniCel Dxl 800 Access Immunoassay Analyzer - Dxl 800 Access Immunoassay Analyzer W/Dual Gantry - Dxl 800 Access Immunoassay Analyzer W/Spot B	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	In vitro diagnostic devices
3	SA-25-06-25-939	Medtronic CareLink™ SmartSync™ Device Manager (SmartSync)	Medtronic SA	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	Active Implantable Devices
4	SA-26-06-25-942	ADVIA 120/2120/2120i Hematology Systems	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	In vitro diagnostic devices
5	SA-25-06-25-940	Certain GE MR systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	Diagnostic and therapeutic radiation devices
6	SA-19-06-25-934	aPTT Screen cobas t 600T, aPTT Lupus cobas t 600T, aPTT cobas t 600T	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	In vitro diagnostic devices
7	SA-24-06-25-937	da Vinci X and Xi Systems	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/439	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-24-06-24-468	BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices