

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2528
Publish date: 06-Jul-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 29-Jun-25
To 05-Jul-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:

* 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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-01-07-25-947	HeartSine Samaritan PAD	HeartSine Technologies Ltd	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
2	SA-18-06-25-932	MRI Systems	Canon Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
3	SA-01-07-25-948	Fine Micro Cannula	Changzhou Shuangma Medical Device Co. Ltd.	Nawat Health Medical Est	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
4	SA-26-06-25-943	HAMILTON-C6	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
5	SA-26-06-25-941	Ransel Glutathione Peroxidase	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-29-06-25-945	Unsaturated Iron Binding Capacity (UIBC) Reagent	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-30-06-25-946	Philips MR Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
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
9	SA-22-01-25-758	Philips Allura and Azurion systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-13-02-25-785	Centricity Universal Viewer and Centricity PACS-IW	GE Healthcare	GE Healthcare	https://ade.sfda.gov	Medical software