

Safety Alerts Weekly Update

Report Reference: WU2436
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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 25-Aug-24
To 31-Aug-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=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 إبذار السلامة:

No. of Safety Alerts: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-25-10-23-118	Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T, Intera 1.5T Power/Pulsar, SmartPath to dStream for 1.5T	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/85	Diagnostic and therapeutic radiation devices
2	SA-28-08-24-575	Alinity i HBsAg Controls, ARCHITECT HBsAg Controls	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov	In vitro diagnostic devices
3	SA-22-08-24-568	BIOFIRE FILMARRAY 2.0 and TORCH System	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov	In vitro diagnostic devices
4	SA-26-08-24-570	CADD Medication Cassette Reservoirs	Smiths Medical..	AL-KAMAL Import	https://ade.sfda.gov	Electro mechanical medical devices
5	SA-26-08-24-571	CADD-Solis Li-ion Rechargeable Battery Packs	Smiths Medical..	AL-KAMAL Import	https://ade.sfda.gov	Electro mechanical medical devices
6	SA-28-08-24-572	EasyConnect Adapter for 2 to 4 Lumen Jet Catheter	CARL REINER GmbH	Al Khateeb United Trading Est.	https://ade.sfda.gov	Anaesthetic and respiratory devices
7	SA-13-08-24-558	FACSDuet Sample Preparation System	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov	In vitro diagnostic devices
8	SA-25-10-23-117	Multiva 1.5T MR Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/85	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-23-08-24-569	Philips Azurion, Allura Xper, Integris and MultiDiagnost Eleva	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/	Diagnostic and therapeutic radiation devices