

Safety Alerts Weekly Update

Report Reference:

WU2533

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10-Aug-25

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 **03-Aug-25**

من

To **09-Aug-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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-03-08-25-984	Accez Monthly Color Contact Lenses	MI GWANG CONTACT LENS CO., LTD.	Nahdi Medical Company	https://ade.sfda.gov	Ophthalmic and optical devices
2	SA-31-07-25-983	Philips Azurion and Allura with 1 Phase UPS	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
3	SA-03-08-25-985	DxC 500i Clinical Analyzer	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov	In vitro diagnostic devices
4	SA-04-08-25-986	WATCHMAN TruSeal™ Access System, WATCHMAN FXD Curve™ Access System	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov	Non-active implantable devices
5	SA-04-08-25-987	Surdial X Dialysis Machine	Nipro Corporation.	Al-Faisaliah Medical System	https://ade.sfda.gov	Electro mechanical medical devices
6	SA-04-08-25-989	SKULL TRACTION TONG LARGE	Aesculap	Gulf Medical Co.	https://ade.sfda.gov	Reusable devices
7	SA-04-08-25-988	Allura Xper systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
8	SA-06-08-25-991	FLEX Monoclonal Mouse Anti-Human CD20cy Clone L26 (Omnis)	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-06-08-25-990	VITROS® Chemistry Products LAC Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov	In vitro diagnostic devices
10	SA-30-07-25-982	Access hsTnl Reagent Kit	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov v.sa/Fsca/PublishD	In vitro diagnostic devices