

Safety Alerts Weekly Update

Report Reference: WU2529
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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 06-Jul-25 من
To 12-Jul-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:

* تأمل 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: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-07-07-25-954	QUANTA Flash® Centromere Controls	Werfen..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
2	SA-29-06-25-944	Invacare Birdie lifter	Invacare France operations SAS	Regulatory Standards Consultation Office	https://ade.sfda.gov.sa/Fsca/Publish	Assistive products for persons with disability
3	SA-06-07-25-952	Q-Link 13 components and LikoScale Adapter Kits	Hill Rom Inc	Medical regulations gate	https://ade.sfda.gov.sa/Fsca/Publish	Assistive products for persons with disability
4	SA-06-07-25-951	InPen App	Medtronic MiniMed...	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Medical software
5	SA-24-06-25-935	Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
6	SA-03-07-25-950	Urinalysis Control Level 2	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
7	SA-01-07-25-949	Philips Allura R8.2.x System	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
8	SA-06-07-25-953	Liquid Urine Control Level 3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
9	SA-09-07-25-956	Blood Transfusion Set	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices

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10	SA-08-07-25-955	Heater Unit HU 35	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
11	SA-25-10-23-117	Multiva 1.5T MR Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices