

Safety Alerts Weekly Update

Report Reference: WU26 18
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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 19-Apr-26 من
To 25-Apr-26 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=7KN979YXNHPPRENX>



* 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: 8 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-20-04-26-1363	3Dimensions Mammography System, Selenia Dimensions Mammography System	Hologic Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
2	SA-21-04-26-1364	URINALYSIS CONTROL - LEVEL 2.	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov	In vitro diagnostic devices
3	SA-29-03-26-1294	Artisan Periodic Acid-Schiff Stain Kit, Artisan Alcian Blue/PAS Stain Kit, Artisan PAS-Green Stain Kit, and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit	Dako North America Inc	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/797	In vitro diagnostic devices
4	SA-21-04-26-1366	Allia IGS systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
5	SA-14-04-26-1356	Rx Modena	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-22-04-26-1368	Injector Syringe Dual	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
7	SA-07-08-23-23	Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-23-02-26-1258	Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Anaesthetic and respiratory devices