

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2526

الرقم المرجعي للتقرير:

Publish date: 22-Jun-25

تاريخ النشر:

below is the weekly report of Safety Alerts for the period:

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 15-Jun-25

من

To 21-Jun-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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-04-06-25-921	Hugo™ Robotic-Assisted Surgery (RAS)	Medtronic SA	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/429	Electro mechanical medical devices
2	SA-12-06-25-924	LIFEPEARL™ Drug Elutable Microspheres	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/429	Single-use devices
3	SA-11-06-25-923	LIAISON Biotrin Parvovirus B19 IgM	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishDetails/436	In vitro diagnostic devices
4	SA-15-06-25-925	Guedel Airways	Intersurgical Limited	Al Hammad Medical Services	https://ade.sfda.gov.sa/Fsca/PublishDetails/436	Anaesthetic and respiratory devices
5	SA-18-06-25-933	Contact lenses Bella Elite - Green Olive	INTEROJO INC.	Juman optics Company	https://ade.sfda.gov.sa/Fsca/PublishDetails/436	Reusable devices
6	SA-16-06-25-926	RX Daytona + with ISE/ RX Daytona + without ISE / RX Imola / RX Modena /RX Monaco / RX Misano	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/429	Laboratory equipment
7	SA-16-06-25-927	Dexcom One Glucose Receiver, Dexcom G7 Glucose Receiver, Dexcom One+ Glucose Receiver Dexcom G6 Glucose Receiver	DexCom Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/436	Diagnostic and therapeutic radiation devices
8	SA-17-06-25-929	VITROS Chemistry Products OP Reagent	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/436	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-17-06-25-928	VITROS Chemistry Products Performance Verifiers	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
10	SA-18-06-25-931	Evidence + Analyser	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	Laboratory equipment
11	SA-17-06-25-930	SPRINTER CART (XL)	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ade.sfda.gov.sa/Fsca/PublishD	Hospital hardware
12	SA-21-03-24-338	OmniLab Advanced + (OLA+)	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices