

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2531
Publish date: 27-Jul-25

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 20-Jul-25
To 26-Jul-25

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=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:



Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

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-21-07-25-966	Dexcom G7 App & Dexcom One + App	DexCom Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Diagnostic and therapeutic radiation devices
2	SA-21-07-25-965	VentStar Helix heated (N) Plus, VentStar Helix dual b (N) Plus and VentStar Aquapor dual b (N) Plus	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Single-use devices
3	SA-21-07-25-967	Ultraview DM3 Monitor and Spacelabs DM4	Spacelabs Healthcare Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Diagnostic and therapeutic radiation devices
4	SA-22-07-25-968	Affirm Prone Breast Biopsy System	Hologic Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Diagnostic and therapeutic radiation devices
5	SA-22-07-25-971	PVC Tubing (hose) used in Ambulatory Blood Pressure Monitoring (ABPM) Cuffs	Spacelabs Healthcare Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Reusable devices
6	SA-22-07-25-970	Multiple X-ray diagnostic equipments	Shimadzu Corporation	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/473	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
7	SA-22-07-25-969	- Digital Radiography System RADspeed safire - RADspeed Pro - CEILING TUBE SUPPORT CH-200 - CEILING TUBE SUPPORT CH-200M	Shimadzu Corporation	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/478	Diagnostic and therapeutic radiation devices
8	SA-24-07-25-972	Massage table Elemental REF ICE S4.F0 Massage table Elemental REF ICE S3.F0 Safari Massage table (Jaguar) REF P5.F4	N/A.....	Care Techniques Est.	https://ade.sfda.gov.sa/Fsca/PublishDetails/479	Electro mechanical medical devices