

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2523

الرقم المرجعي للتقرير:

Publish date: 01-Jun-25

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 25-May-25

من

To 31-May-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: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-22-05-25-904	MAGLIFE RT-1	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/409	Diagnostic and therapeutic radiation devices
2	SA-22-05-25-903	Liquid Assayed Chemistry Control Premium Plus Level 2/3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	In vitro diagnostic devices
3	SA-25-05-25-908	AlloSeq cfDNA	caredx Pty Ltd...	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	In vitro diagnostic devices
4	SA-22-05-25-905	Trilogy Evo - Trilogy Evo O2 - Trilogy EV300 - Trilogy Evo Universal	Philips Respironics California	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	Anaesthetic and respiratory devices
5	SA-26-05-25-909	Newport HT Ventilator with Accessories, Plus model; Newport HT70™ Plus Ventilator with oxygen monitoring, SpO2 monitoring, on-airway flow sensor;	Covidien LLC...	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	Anaesthetic and respiratory devices
6	SA-27-05-25-911	Consumables from MEDTRON AG	MEDTRON AG	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	Single-use devices
7	SA-27-05-25-910	Draeger Filter/HME - SafeStar 90 Plus, SafeStar 60A Plus, SafeStar 55 Plus, TwinStar HEPA Plus	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/411	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-28-05-25-913	Extended Tip Applicator (XTA)	Integra LifeSciences	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/415	Single-use devices
9	SA-28-05-25-914	VITROS 4600 Chemistry System - VITROS 5600 Integrated System - VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/415	Laboratory equipment
10	SA-23-05-25-906	Panorama HFO	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/142	Diagnostic and therapeutic radiation devices
11	SA-21-03-24-339	All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/142	Anaesthetic and respiratory devices