

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2619

الرقم المرجعي للتقرير:

Publish date: 03-May-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 26-Apr-26

من

To 02-May-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:

* تأمل 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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-26-04-26-1373	Kiwi Complete Vacuum Delivery System	Laborie Medical Technologies, Corp.	MEDICAL INNOVATIONS EST.	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
2	SA-23-04-26-1369	Q-FLOW SURGICAL LIGHT	Merivaara Corp	Omar Saeed Al-Amoudi Sons Co. (L.L.C.)	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
3	SA-22-04-26-1367	Afinion Hba1c	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
4	SA-25-04-26-1371	Da Vinci SP1098 Patient Side Cart (PSC) E-Brake Retainer Pin	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
5	SA-26-04-26-1374	- Proclaim™ Implantable Pulse Generator - Proclaim™ Implantable Pulse Generator (DRG) - Infinity™ Implantable Pulse Generator - Infinity Implantable Pulse Generator	Abbott Medical ..	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/Publish/Details/803	Active Implantable Devices
6	SA-27-04-26-1377	CASE v7 Systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
7	SA-28-04-26-1378	ApexPro CARESCAPE Telemetry Server v5.0 and v6.0 with CARESCAPE Central Station or CIC Pro Clinical Information Center	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/805	Diagnostic and therapeutic radiation devices
8	SA-27-04-26-1376	Philips Allura and Azurion systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
9	SA-27-04-26-1375	Philips Azurion Systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
10	SA-26-04-26-1372	Atlan Anaesthesia Workstations	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Anaesthetic and respiratory devices