

Safety Alerts Weekly Update

التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2437

الرقم المرجعي للتقرير:

Publish date:

08-Sep-24

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From **01-Sep-24**

من

To **07-Sep-24**

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=CTLNDA7ARTRDHMA>



* 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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إنذار السلامة:

No. of Safety Alerts: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-03-09-24-583	Automated Compounding Device Inlet	Baxter Healthcare	Baxter AG	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
2	SA-02-09-24-582	Battery corpuls cpr (LiPo)	GS Elektromedizinische Geräte G. Stemple GmbH	Al Khateeb United Trading Est.	https://ade.sfda.gov.sa/Fsca/PublishD	Reusable devices
3	SA-29-08-24-577	CADD-Solis AC Adapter	Smiths Medical..	AL-KAMAL Import	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
4	SA-02-09-24-581	IntelliVue Patient Monitor Power Supply	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
5	SA-02-09-24-580	MR System Patient Support	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
6	SA-30-08-24-578	Multiple products	Alcon Laboratories Inc....	Alcon Pharmaceuticals Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	Ophthalmic and optical devices
7	SA-28-08-24-573	NOVACLONE™ Anti-D IgM + IgG Monoclonal Blend	Dominion Biologicals Ltd.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
8	SA-31-08-24-579	Software App 9735762 Stealth S8 Application	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
9	SA-29-08-24-576	Welch Allyn Configuration Tool	Welch Allyn, Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices