

Safety Alerts Weekly Update

Report Reference: WU2442
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التقرير الأسبوعي لإنذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 06-Oct-24
To 12-Oct-24

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=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 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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-09-10-24-621	3-Way Stopcock.	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
2	SA-08-10-24-618	Atlan A100 Atlan A300 Atlan A300 XL Atlan A350 Atlan A350 XL	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/132	Anaesthetic and respiratory devices
3	SA-08-10-24-617	MR systems with FlexTrak docking interface	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
4	SA-08-10-24-616	paraPAC 300 paraPAC plus 310	Smiths Medical..	AL-KAMAL Import	https://ade.sfda.gov	Anaesthetic and respiratory devices
5	SA-07-10-24-614	Pneupac paraPAC	Smiths Medical..	AL-KAMAL Import	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
6	SA-09-10-24-619	Rx Imola	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-02-10-24-611	TruSystem 7000 Surgical Table	Baxter Healthcare	Baxter AG	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
8	SA-07-10-24-615	UroPass- Ureteral Access Sheath	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-06-10-24-613	VITROS Immunodiagnostic Products Anti-HTLV I/II Controls	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.go	In vitro diagnostic devices