

### Safety Alerts Weekly Update

Report Reference: WU2549  
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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 23-Nov-25 من  
To 29-Nov-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:

- 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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-24-11-25-1159	SL SOLUTION, 1ML	Copan Italia S.p.A	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
2	SA-25-11-25-1160	3M Cavilon™ Durable Barrier Cream	3M Health Care....	Solventum Arabia Trading Company	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
3	SA-24-11-25-1157	Central Venous Catheter Set (Double Lumen)	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
4	SA-20-11-25-1155	Xpert® BCR-ABL Ultra	Cepheid...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
5	SA-24-11-25-1158	Accella therapy air mattresses (and spare parts associated with Progressa frames)	Hill Rom Inc	Medical regulations gate	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Hospital hardware
6	SA-23-11-25-1156	UniCel Dxl 600 and 800 Analyzers	Beckman Coulter....	DHR Diagnostics Arabia Limited	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
7	SA-25-11-25-1161	Alinity ci-series System Control Module (SCM).	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
8	SA-13-11-25-1145	Clearway 2	BREAS Medical AB	Regulatory Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Anaesthetic and respiratory devices
9	SA-10-10-25-1088	Bicarbonate	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-17-08-25-1006	Multiple MRI systems	Siemens Medical Solutions	Siemens Medical Solutions	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices