

### Safety Alerts Weekly Update

Report Reference: WU2546  
Publish date: 09-Nov-25

### 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 02-Nov-25 من  
To 08-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: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-05-11-25-1132	REANIBEX 300/ REANIBEX 500	Osatu S.Coop.	aldawaa medical services	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
2	SA-02-11-25-1123	Access 2 Reaction Vessels	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
3	SA-30-10-25-1121	LGN Tibial Offset Bushing 4MM	Smith & Nephew inc	Smith & Nephew inc	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Non-active implantable devices
4	SA-03-11-25-1124	SLE1500 & INTERFLOW GAS BLENDER	Inspiration Healthcare Limited	Techno-Orbits Establishment	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Anaesthetic and respiratory devices
5	SA-30-10-25-1122	Xpert CT/NG	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
6	SA-03-11-25-1127	Philips IntelliVue Patient Monitors	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
7	SA-03-11-25-1129	Zenition 10 & Zenition 30	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices
8	SA-04-11-25-1131	BD BACTEC™ MGIT™ 960 PZA Kit	BD Biosciences	Becton Dickinson B.V.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
9	SA-03-11-25-1130	KNEO THREADED FASTENING PINS	Groupe Lépine	Dr Mazen Fakeeh Complementary Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-06-11-25-1134	Rocket Seldinger Chest Drain Kits	Rocket Medical	Modern Quality Est.	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Single-use devices
11	SA-29-08-25-1030	ACCOLADE Family of Pacemakers and CRT-Ps	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Active Implantable Devices