

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:** WU2507  
**Publish date:** 09-Feb-25

**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-Feb-25 من  
To 08-Feb-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:

\* 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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-02-02-25-772	Access 2 Immunoassay Analyzer	Beckman Coulter UK Ltd	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
2	SA-02-02-25-770	Access Erythropoietin (EPO)	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
3	SA-23-01-25-761	Alinity m System. An in vitro diagnostic medical device (IVD)	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
4	SA-03-02-25-773	ARTIS One Angiographic X-Ray System	Siemens Healthcare GmbH	Siemens Medical Solutions	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Diagnostic and therapeutic radiation devices
5	SA-02-02-25-769	Dexcom G6 Receiver	DexCom Inc	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
6	SA-26-01-25-765	LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators	LivaNova PLC	cigalah group	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/277">https://ade.sfda.gov.sa/Fsca/PublishDetails/277</a>	Active Implantable Devices
7	SA-26-01-25-766	LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators	LivaNova PLC	cigalah group	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/281">https://ade.sfda.gov.sa/Fsca/PublishDetails/281</a>	Active Implantable Devices
8	SA-06-02-25-776	ORTHO Optix™ Reader BioVue	Ortho-Clinical Diagnostics	Samir Photographic Supplies 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
9	SA-15-01-25-743	ORTHO VISION® and ORTHO VISION® Max Analyzers	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/275">https://ade.sfda.gov</a>	Laboratory equipment
10	SA-03-02-25-775	Pipeline Vantage Embolization Device with Shield Technology	Micro Therapeutics Inc (DBA ev3 Neurovascular )	Medtronic Saudi Arabia	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/275">https://ade.sfda.gov</a>	Single-use devices
11	SA-03-02-25-774	SIGNA™ Creator - SIGNA™ Explorer - SIGNA™ MR380 - SIGNA™ MR355 - SIGNA™ MR360 - Brivo MR355 - Optima MR360 MR systems	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/275">https://ade.sfda.gov.sa/Fsca/PublishDetails/275</a>	Diagnostic and therapeutic radiation devices
12	SA-02-02-25-771	TBS iNsight	medimaps group SA	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/275">https://ade.sfda.gov.sa/Fsca/PublishDetails/275</a>	Medical software