

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:** WU2519  
**Publish date:** 04-May-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 27-Apr-25  
To 03-May-25

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=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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-13-04-25-852	Glooko Web Application	Glooko AB	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Medical software
2	SA-28-04-25-875	SIMEOX_H_EU	PHYSIOASSIST SAS	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
3	SA-23-04-25-871	CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pumps Thermal Damage	Smiths Medical..	AL-KAMAL Import	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
4	SA-23-04-25-872	CADD-Solis™ and CADD-Solis VIP™ Ambulatory Infusion Pumps.	Smiths Medical..	AL-KAMAL Import	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
5	SA-27-04-25-874	Access Testosterone Reagent Kit	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
6	SA-28-04-25-876	Hugo™ Robotic-Assisted Surgery (RAS)	Medtronic Inc.	Medtronic Saudi Arabia	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
7	SA-17-04-25-860	ID NOW™ COVID-19 2.0, ID NOW™ RSV & ID NOW™ Influenza A & B 2	Abbott Diagnostic International Ltd	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-24-03-25-826	Carestation 620/650/650c and 750/750c Anesthesia Systems	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Anaesthetic and respiratory devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-12-03-25-810	Venue Go / Venue Fit Ultrasound systems	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	Diagnostic and therapeutic radiation devices