

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2538
Publish date: 14-Sep-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 07-Sep-25
To 13-Sep-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=4MT7LEJ3DFP7H8LI>



* 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:

Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

No. of Safety Alerts: 14 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-20-08-25-1018	GETINGE 88-5 Washer disinfectant	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
2	SA-11-09-25-1044	ARGUS PB-3000	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
3	SA-09-09-25-1040	Atellica CH Urinary/Cerebrospinal Fluid Protein	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
4	SA-04-09-25-1034	ID-DiaPanel and ID-DiaPanel-P	Bio-Rad Medical Diagnostics	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-09-09-25-1041	AW Server	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
6	SA-05-09-25-1035	Philips Allura Xper, Allura CV20 and Allura Centron Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
7	SA-10-09-25-1043	Charging unit mounted W/T AC TS7500	Baxter Healthcare	Baxter AG	https://ade.sfda.gov.sa/Fsca/PublishD	Hospital hardware
8	SA-02-09-25-1031	Atlan anaesthesia workstations	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
9	SA-05-09-25-1036	Philips Allura Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-07-09-25-1037	Liquid Assayed Specific Protein Control 1/2/3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov	In vitro diagnostic devices
11	SA-07-09-25-1038	STA Liatest D-Di Plus	Diagnostica Stago S.A.S.	Diagnostic Saudi Arabia Trading Company	https://ade.sfda.gov v.sa/Fsca/PublishD	In vitro diagnostic devices
12	SA-08-09-25-1039	Vyntus Devices with SNIP/RHINO Option	Jaeger Medical	Bio Standards	https://ade.sfda.gov	Anaesthetic and respiratory devices
13	SA-11-09-25-1046	DEFIGARD HD-7	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov v.sa/Fsca/PublishD	Electro mechanical medical devices
14	SA-10-09-25-1042	Vista 120/120 S monitor	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov v.sa/Fsca/PublishD	Electro mechanical medical devices