

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2539

الرقم المرجعي للتقرير:

Publish date: 21-Sep-25

تاريخ النشر:

below is the weekly report of Safety Alerts for the period:

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 14-Sep-25

من

To 20-Sep-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: 16 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-16-09-25-1055	CONFIRM anti-Estrogen Receptor (ER) (SP1) Rabbit Monoclonal Primary Antibody 50 and 250 test packs	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	In vitro diagnostic devices
2	SA-12-09-25-1047	DxFLEX Flow Cytometer	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	In vitro diagnostic devices
3	SA-16-09-25-1059	VIDAS® CK-MB	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	In vitro diagnostic devices
4	SA-16-09-25-1058	VIDAS® HIV DUO AG/AB (HIV)	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	In vitro diagnostic devices
5	SA-04-09-25-1033	- ID-Anti-S - Test serum ID-Anti-M, N, S, s, Fya, Fyb	Bio-Rad Medical Diagnostics	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	In vitro diagnostic devices
6	SA-15-09-25-1054	RENZAN™M Peripheral Stent System	Terumo Cardiovascular Systems Corp	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	Non-active implantable devices
7	SA-14-09-25-1049	Certain Nuclear Medicine Systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	Diagnostic and therapeutic radiation devices
8	SA-15-09-25-1053	TactiFlex Ablation Catheter, Sensor Enabled	Abbott Medical ..	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/548	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-15-09-25-1051	ROTEM® sigma ROTROL P	Tem Innovations GmbH.	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
10	SA-17-09-25-1060	Dxl 9000 Access Immunoassay Analyzer	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
11	SA-15-09-25-1052	Heater Unit HU 35	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
12	SA-14-09-25-1048	Bronchofiberscope, Bronchovideoscope	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
13	SA-12-08-25-998	SOPHIE 2020 ventilator	Fritz Stephan GmbH.	Al Khateeb United Trading Est.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
14	SA-16-09-25-1057	MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
15	SA-16-09-25-1056	Datascope Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD etails/554	Electro mechanical medical devices
16	SA-04-08-25-987	Surdial X Dialysis Machine	Nipro Corporation.	Al-Faisaliah Medical System	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices