

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2548

الرقم المرجعي للتقرير:

Publish date: 23-Nov-25

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 16-Nov-25

من

To 22-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:**

*** 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-13-11-25-1146	Sterile Connectors for Blood Management	Mays Alsaudiah Lilmuntajat Alttabiah Almahdoodeh	Mays Alsaudiah Lilmuntajat Alttabiah Almahdoodeh	https://ade.sfda.go	Single-use devices
2	SA-18-11-25-1150	NATEJAH One Step Malaria (Pf/Pan) Rapid Test	Natejah Industrial Company	Natejah Industrial Company	https://ade.sfda.go	In vitro diagnostic devices
3	SA-12-11-25-1144	ORTHO VISION™ BioVue Analyzers	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.go	In vitro diagnostic devices
4	SA-13-11-25-1148	DEFIGARD Touch7 monitor and defibrillator	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.go	Electro mechanical medical devices
5	SA-17-11-25-1149	Carestation 600 and 700 Series Anesthesia Systems with affected Power Management Board (PMB)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/629	Diagnostic and therapeutic radiation devices
6	SA-19-11-25-1153	Elecsys Anti-TSHR assay	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/629	In vitro diagnostic devices
7	SA-05-11-25-1133	Model 8103 Symmetry VNS Therapy Generators	LivaNova PLC	cigalah group	https://ade.sfda.go	Active Implantable Devices
8	SA-19-11-25-1154	Multiple MR Systems with software versions R5.2 through R5.8.1.	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/629	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-17-08-25-1006	Multiple MRI systems	Siemens Medical Solutions	Siemens Medical Solutions	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices