

Safety Alerts Weekly Update

التقرير الأسبوعي لإبذارات السلامة

Report Reference: WU2505
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الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 19-Jan-25
To 25-Jan-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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إبذار السلامة:

No. of Safety Alerts: 17 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-21-01-25-751	- IMMULITE 2000 Analyzer - IMMULITE 2000 XPi Analyzer	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	https://ade.sfda.go	In vitro diagnostic devices
2	SA-22-01-25-757	AD7 and AD7X patient tables which are part of Philips Allura and Azurion systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.go/v.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
3	SA-21-01-25-752	AESCLAP Aicon® Sterile Container System	Aesculap	Gulf Medical Co.	https://ade.sfda.go	Reusable devices
4	SA-16-01-25-745	Atellica CH Revised C-Reactive Protein (RCRP)	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.go	In vitro diagnostic devices
5	SA-16-01-25-744	Butterfly iQ+ and iQ3 used with theButterfly iQ Application	Butterfly Network, Inc.	Bio Standards	https://ade.sfda.go	Diagnostic and therapeutic radiation devices
6	SA-22-01-25-756	Cardinal Health Presource Kits:	Cardinal Health 200, LLC..	Medical Regulations Gate	https://ade.sfda.go/v.sa/Fsca/PublishD	Reusable devices
7	SA-20-01-25-750	Medima Infusion Pump	ICU Medical, Inc	AL-KAMAL Import	https://ade.sfda.go/v.sa/Fsca/PublishD	Electro mechanical medical devices
8	SA-20-01-25-749	Medima P100, P200, and P300 Volumetric infusion Pumps	ICU Medical, Inc	AL-KAMAL Import	https://ade.sfda.go	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-21-01-25-755	Multi Sentry 125 Uninterruptible Power Supply used with with certain Philips CT system models	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
10	SA-21-01-25-754	Multiva 1.5T	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
11	SA-19-01-25-748	Optipac Bone Cement	Zimmer Biomet	Zimmer Biomet Asel Alarabia	https://ade.sfda.gov.sa/Fsca/PublishD	Non-active implantable devices
12	SA-21-01-25-753	Oral Dispensing Syringe White Plunger with Tip Cap	Alshifa Medical Products Co CJS	alshifa medical syringe	https://ade.sfda.gov	Single-use devices
13	SA-19-01-25-746	PENTAX MEDICAL Video Processor EPK-i8020c and PENTAX Medical Video Endoscopes of the i20c series.	Hoya Corporation	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/253	Electro mechanical medical devices
14	SA-22-01-25-758	Philips Allura and Azurion systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
15	SA-19-01-25-747	PS-10	Sysmex Corporation	Sysmex LLC One Person Co	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
16	SA-23-01-25-760	Software update for the intensive care ventilator elisa 300/500/600/800/800VIT	Lowenstein Medical GmbH &Co.KG	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
17	SA-30-09-24-608	Zenition 50 and Zenition 70 systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices