

Safety Alerts Weekly Update

Report Reference: WU2434
Publish date: 18-Aug-24

التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 11-Aug-24
To 17-Aug-24

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=CTLNDA7ARTRDHM>



* Role of contact officer:

- 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.

* مسؤولية ضابط الاتصال:

- 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 إذار السلامة:

No. of Safety Alerts: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-12-08-24-553	- VERCISE GENUS R16 IPG KIT - VERCISE GENUS R32 IPG KIT	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/Publish	Active Implantable Devices
2	SA-12-08-24-551	Airvo 3	Fisher & Paykel Healthcare Limited	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	Anaesthetic and respiratory devices
3	SA-11-08-24-549	Aisys CS2, Avance CS2, Avance CS2 Pro, Aisys, Avance, Amingo, Aespire 100, Aespire View, Aespire 7900, and Aespire 7100 anesthesia devices equipped with the Auxiliary Common Gas Outlet (ACGO)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publish/Details/62	Anaesthetic and respiratory devices
4	SA-11-08-24-550	Centricity PACS 4.0	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publish	Medical software
5	SA-08-08-24-548	Centricity Universal Viewer Zero Footprint Client	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
6	SA-12-08-24-554	DAILIES TOTAL1, DAILIES TOTAL1 for Astigmatism	Alcon Laboratories Inc....	Alcon Pharmaceuticals Ltd	https://ade.sfda.gov.sa/Fsca/Publish	Ophthalmic and optical devices
7	SA-13-08-24-555	HemosIL® AcuStar ADAMTS13 Activity	Instrumentation Laboratory.	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-12-08-24-552	HMC feeding, aspiration and feeding/aspiration tubes	HMC PREMEDICAL SPA	Al Hammad Medical Services	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
9	SA-29-07-24-538	Impella CP	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
10	SA-04-08-24-540	Luisa, Tivan LS, Life One (LM150TD) Ventilators	Lowenstein Medical GmbH &Co.KG	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	Anaesthetic and respiratory devices