

Safety Alerts Weekly Update

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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 28-Jul-24
To 03-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=CTLNDA7ARTRDHMA>



* 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 إبذار السلامة:

No. of Safety Alerts: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-03-07-24-490	ABL800 Basic and ABL8XX FLEX analysers	Radiometer Medical	Salehiya Trading Est.	https://ade.sfda.gov	In vitro diagnostic devices
2	SA-25-07-24-531	Azurion systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
3	SA-25-07-24-530	BD Phoenix™ M50 & BD Phoenix™ 100 Instruments	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov	In vitro diagnostic devices
4	SA-25-07-24-529	CARDIOVIT AT-180	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov	Electro mechanical medical devices
5	SA-26-07-24-532	FREEGO ENTERAL FEEDING PUMP	Zevex International Inc	Abbott Saudi Arabia for Trading	https://ade.sfda.gov	Electro mechanical medical devices
6	SA-08-07-24-501	HeartMate 3 LVAS	Abbott..	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov	Active Implantable Devices
7	SA-28-07-24-536	IRISpec CA/CB/CC.	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov	In vitro diagnostic devices
8	SA-28-07-24-533	McGRATH MAC video laryngoscope	Medtronic SA	Medtronic Saudi Arabia	https://ade.sfda.gov	Electro mechanical medical devices
9	SA-21-07-24-523	PE Dynamic Inlet-PLC	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-25-07-24-528	V90 electronic vaporizer (for used with A9 Anesthesia system)	Shenzhen Mindray Bio-Medical Electronics Co.,	Dar Batterjee Company Ltd	https://ade.sfda.gov	Anaesthetic and respiratory devices
11	SA-28-07-24-535	XF-1600	Sysmex Corporation	Sysmex LLC One Person Co	https://ade.sfda.gov	In vitro diagnostic devices