

Safety Alerts Weekly Update

Report Reference: WU2447
Publish date: 17-Nov-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 10-Nov-24
To 16-Nov-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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-11-11-24-670	ACURATE neo2™ Aortic Valve Systems	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.g	Non-active implantable devices
2	SA-05-11-24-661	Atellica CH Reaction Ring Cuvette Segment	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.g	In vitro diagnostic devices
3	SA-06-11-24-664	Atellica CH β2-Microglobulin (B2M)	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.g	In vitro diagnostic devices
4	SA-13-11-24-673	Atellica CI Analyzer	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.g ov.sa/Fsca/Publish	In vitro diagnostic devices
5	SA-07-11-24-667	Atellica IM Analyzer ADVIA Centaur XP System ADVIA Centaur XPT System ADVIA Centaur CP System	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.g ov.sa/Fsca/Publish Details/179	In vitro diagnostic devices
6	SA-14-11-24-674	Atellica IM Total Thyroxine	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.g ov.sa/Fsca/Publish	In vitro diagnostic devices
7	SA-06-11-24-662	Cordis SELUTION SLRTM 018 PTA 3.0 mm X 100 mm Balloon Catheters	Cordis Corporation,	ATTIEH MEDICO LTD	https://ade.sfda.g ov.sa/Fsca/Publish	Single-use devices
8	SA-14-11-24-675	Erytra Eflexis Analyser	Grifols-Spain	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.g ov.sa/Fsca/Publish	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-10-11-24-668	LIAISON Q.S.E.T. Device Plus	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
10	SA-13-11-24-672	Philips Allura Xper R7.6- R8.1 systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
11	SA-07-11-24-666	SIL-1000-S, SIL-2000-S, SIL-5000-S Silicone Oil - Prefilled 10ml syringes	D.O.R.C. Dutch Ophthalmic Research Center	Albasar For Medical Supplies	https://ade.sfda.gov.sa/Fsca/Publish	Ophthalmic and optical devices
12	SA-12-11-24-671	VITRA 810	Quantel Medical	First Gulf Co.	https://ade.sfda.gov.sa/Fsca/Publish	Ophthalmic and optical devices