

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference:

WU2630

الرقم المرجعي للتقرير:

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19-Jul-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 12-Jul-26

من

To 18-Jul-26

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=7KN979YXNHPPRENX>



* 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: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-15-07-26-1471	Covidien Shiley™ Disposable Decannulation Plug	Covidien LLC....	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	Single-use devices
2	SA-12-07-26-1462	EVE family and Oxylog 600	Fritz Stephan GmbH.	Al Khateeb United Trading Est.	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	Anaesthetic and respiratory devices
3	SA-15-07-26-1470	Surgipro™, Surgipro II™, Dermalon™, V-Loc™ 90 and 180 Suture Products	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	Single-use devices
4	SA-09-07-26-1461	3M Comply Lead Free Steam Indicator Tape	3M Health Care.....	Solventum Arabia Trading Company	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	Single-use devices
5	SA-09-07-26-1460	cobas® b 123 Sensor Cartridge	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	In vitro diagnostic devices
6	SA-12-07-26-1463	DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	In vitro diagnostic devices
7	SA-12-07-26-1465	Atellica CI Analyzer, Atellica IM Analyzer, ADVIA Centaur XP System & ADVIA Centaur XPT System	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	In vitro diagnostic devices
8	SA-12-07-26-1464	DxC 500i Clinical Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/891	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-13-07-26-1467	Medline Convenience Kits containing all sizes of Medline Red Rubber Intermittent Catheters	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/893	Single-use devices
10	SA-15-07-26-1469	B. Braun Aesculap Silver Graft® and Silver Graft® Helix vascular prostheses.	B Braun Surgical SA	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/893	Non-active implantable devices
11	SA-15-07-26-1468	Getinge Poladus 150 H1/H2	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/893	Electro mechanical medical devices