

Safety Alerts Weekly Update

Report Reference: WU2428
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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 30-Jun-24
To 06-Jul-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	SFDA-0049-2024	3-Way Stopcock with/witout Extension Tube.	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ncmdr.sfda	Single-use devices
2	SA-02-07-24-489	BIOFIRE TORCH Base System	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
3	SA-03-07-24-491	Capio SLIM Suture Capturing Device	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ncmdr.sfda	Single-use devices
4	SA-25-06-24-476	iLED 7 Ceiling Single Surgical Light	Baxter Healthcare	Baxter AG	https://ncmdr.sfda	Electro mechanical medical devices
5	SA-30-06-24-484	Luminos Agile Max, Luminos dRF Max, LUMINOS Lotus Max with display ceiling suspension and Multitom Rax with display wall suspnsion	Siemens Healthcare GmbH	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21111	Diagnostic and therapeutic radiation devices
6	SA-27-06-24-482	Puritan Bennett™ 560 Ventilator - Puritan Bennett™ 520 Ventilator	Covidien LLC....	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	Anaesthetic and respiratory devices
7	SA-27-06-24-481	Rx Imola	Radox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-30-06-24-483	Spectra Optia Apheresis System	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
9	SA-26-06-24-479	Synchro SELECT Guidewire, Synchro 10 and 14 Guidewire, Synchro2 Guidewire	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
10	SA-01-07-24-487	VENTANA anti-CD10 (SP67) Rabbit Monoclonal Primary Antibody	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices