

Safety Alerts Weekly Update

التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2423

الرقم المرجعي للتقرير:

Publish date:

02-Jun-24

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 26-May-24

من

To 01-Jun-24

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: 13 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-26-05-24-428	2nd Generation CentriMag Primary Console	Abbott..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
2	SA-30-05-24-437	731 ZOLL Ventilators with MRI compatibility	ZOLL Medical Corporation	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda.gov.sa/Secure/CA	Anaesthetic and respiratory devices
3	SA-26-05-24-429	DS-EIA-ANTI-TOXO-M (capture)	RPC Diagnostic Systems	Excellence Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
4	SA-20-05-24-420	EIT PLIF	EIT Emerging Implant Technologies GmbH	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
5	SA-26-05-24-427	Immunoglobulin M (IgM)	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
6	SA-30-05-24-436	MiniMed™ 600 and 700	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
7	SA-29-05-24-433	multiFiltratePRO	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
8	SA-29-05-24-435	Mutars RS Stem and Mutars RS Extension Sleeve	Implantcast	AlMafsal Medical Company	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
9	SFDA-0046-2024	SACO LUBRICANT GEL, 5ml	SAHHA FACTORY COMPANY FOR SOLUTION	SAHHA FACTORY COMPANY FOR SOLUTION MEDICAL	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SFDA-0047-2024	VAGINAL EXAMINATION GEL	SAHHA FACTORY COMPANY FOR SOLUTION	SAHHA FACTORY COMPANY FOR SOLUTION MEDICAL	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
11	SA-27-05-24-430	VasoView HemoPro Endoscopic Vessel Harvesting Systems	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
12	SA-23-05-24-425	VITROS Immunodiagnostic Products Anti-HBs Reagent Packl VITROS Immunodiagnostic Products Anti-HBs Calibrators	QuidelOrtho..	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	In vitro diagnostic devices
13	SA-23-05-24-426	Wired Avalon Ultrasound Transducer	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices