

Safety Alerts Weekly Update

Report Reference:

WU2412

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17-Mar-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-Mar-24

من

To 16-Mar-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 إنبذار 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-29-02-24-306	Captus 4000e	Mirion Technologies (Capintec), Inc.	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
2	SA-12-03-24-321	CERVIOS chronOS Wedge-Shaped Cage	Synthes GmbH.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
3	SA-04-03-24-312	Covidien Auto Suture Structural Balloon Trocar & Auto Suture Blunt Tip Trocar	Covidien LLC....	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
4	79378EF85B291	Detachable EndoRetrieval Pouch	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	https://ncmdr.sfda.gov.sa/Secure/CA	Ophthalmic and optical devices
5	SA-03-03-24-308	Digital Diagnostic Mobile X-ray System GM85	Samsung Electronics..	ATTIEH MEDICO LTD	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
6	SA-07-03-24-318	DX-D 100	Agfa NV	CARE and Planning for Hospital Co. Ltd	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
7	SA-13-03-24-323	FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-05-03-24-314	Hydrophilic acrylic intraocular lenses CLARE, QUATUOREVO, CRISTAL, LUCIS Preloaded hydrophobic acrylic intraocular lenses ARTIS Y PL, ARTIS PL E	Cristalens Industrie	Riyadh Medical Services	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20946	Non-active implantable devices
9	SA-12-03-24-319	Perseus A500	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Anaesthetic and respiratory devices
10	SA-12-03-24-320	Rad-G Devices	Masimo Corporation	Masimo International SARL	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
11	SA-13-03-24-322	VITROS Chemistry Products Performance Verifier I and II	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda	In vitro diagnostic devices