

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2617
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الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 12-Apr-26 من
To 18-Apr-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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-10-04-26-1351	Novuma Collagen Stimulating Dermal Filler	BURGEON BIYOTEKNOLOJI VE SAN.TIC.A.S	Marina Arabian Medical Company	https://ade.sfda.g	Non-active implantable devices
2	SA-14-04-26-1360	CHROMOPHARE Softlit Ring Surgical Light System	Stryker Communications.....	Zimmo Trading Establishment.	https://ade.sfda.g	Electro mechanical medical devices
3	SA-12-04-26-1354	Resuscitation Set with APL Valve (Mapleson Systems)	Armstrong Medical Ltd.	Al Khateeb United Trading Est.	https://ade.sfda.g	Single-use devices
4	SA-11-04-26-1353	Mixing Bowl and Spatula, 20-pack	Zimmer Biomet	Zimmer Biomet Asel Alarabia	https://ade.sfda.g	Single-use devices
5	SA-11-04-26-1352	SynchroMed™ Flex Infusion Mode - A810 Clinician Programmer	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.g ov.sa/Fsca/Publish	Active Implantable Devices
6	SA-09-04-26-1350	da Vinci X, Xi systems Universal Surgical Manipulator (USM)	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.g	Electro mechanical medical devices
7	SA-14-04-26-1359	InZone Detachment System	Stryker Neurovascular...	Zimmo Trading Establishment.	https://ade.sfda.g ov.sa/Fsca/Publish	Single-use devices
8	SA-15-04-26-1362	Arrow Hemodialysis Kits & Sets	Arrow International Inc	Gulf Medical Co.	https://ade.sfda.g ov.sa/Fsca/Publish	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-15-04-26-1361	POLARxTM and POLARxTM FIT Cryoablation Balloon Catheters, POLARSHEATHTM Steerable Sheaths, and SMARTFREEZETM Cryoablation System Consoles	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfd.a.gov.sa/Fsca/PublishDetails/790	Single-use devices