

Safety Alerts Weekly Update

Report Reference: WU2453
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التقرير الأسبوعي لإنذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 22-Dec-24 من
To 28-Dec-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 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: 16 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-25-12-24-723	- DLP Pediatric One-Piece Arterial Cannulae - EOPA Arterial Cannula - Select Series Angled Tip Arterial Cannula	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/234	Single-use devices
2	SA-22-12-24-713	- PD-L1 IHC 22C3 pharmDx - PD-L1 22C3 pharmDx Kit (IUO)	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	In vitro diagnostic devices
3	SA-25-12-24-724	AXIOS Stent and Electrocautery Enhanced Delivery System	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	Non-active implantable devices
4	SA-17-12-24-708	Certain Infinia, VariCam/VG/VH, Brivo NM 615, Discovery NM 630, Discovery NM/CT 670, and Optima NM/CT 640 Nuclear Medicine systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	Diagnostic and therapeutic radiation devices
5	SA-23-12-24-714	da Vinci X and Xi Reusable Instruments with Jaws	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	Reusable devices
6	SA-23-12-24-716	Dialysis machines.	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	Electro mechanical medical devices
7	SA-24-12-24-722	Eclipse Mini Eclipse PRO	Spacelabs Healthcare Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/220	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-23-12-24-718	HemosIL Heparin Calibrators	Werfen..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
9	SA-22-12-24-711	Infinity CentralStation	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
10	SA-23-12-24-721	Intermediate ceiling construction (part of the operating theatre lighting system)	KLS Martin GmbH + Co. KG	International Medical Supplies Company	https://ade.sfda.gov.sa/Fsca/Publish/Details/230	Hospital hardware
11	SA-04-11-24-657	Interventional Angiography System	Canon Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
12	SA-23-12-24-715	Oxylog 3000 plus	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/Publish	Anaesthetic and respiratory devices
13	SA-23-12-24-720	PrisMax Systems	Baxter Healthcare	Baxter AG	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
14	SA-19-12-24-710	Single Use Mechanical Lithotripter V	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
15	SA-23-12-24-717	Tenaculum Forceps - Small Graptor on da Vinci X and Xi Tenaculum Forceps and Small Graptor	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish/Details/229	Reusable devices
16	SA-22-12-24-712	THUNDERBEAT Type S Hand Instruments	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices