

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2515
Publish date: 06-Apr-25

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 23-Mar-25
To 05-Apr-25

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=4MT7LEJ3DFP7H8LJ>



* 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:



Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

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-17-03-25-819	Origin Data Management software versions 3.1.0, 3.1.1, 3.1.2, 3.2.0, 3.2.1	Brainlab AG...	Elite Smart Solutions	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
2	SA-24-03-25-828	Nevelia®	SYMATESE	Al-Nozha Medical Est	https://ade.sfda.gov.sa/Fsca/PublishD	Non-active implantable devices
3	SA-26-03-25-831	HemosIL AcuStar ADAMTS13 Activity	Werfen..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov	In vitro diagnostic devices
4	SA-20-03-25-825	Progressa bed surfaces	Hill-Rom, Inc.	Baxter AG	https://ade.sfda.gov.sa/Fsca/PublishD	Hospital hardware
5	SA-20-03-25-823	Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/327	Anaesthetic and respiratory devices
6	SA-24-03-25-826	Carestation 620/650/650c and 750/750c Anesthesia Systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov	Anaesthetic and respiratory devices
7	SA-27-03-25-832	EsophyX® Z+	Merit Medical Systems , Inc.	Al-Nozha Medical Est	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
8	SA-27-03-25-833	Bi-Polar Electrodes used with Scarlet S Device	VIOL CO., Ltd	Gulf Laser Trading Company	https://ade.sfda.gov	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-20-03-25-824	CELL-DYN Ruby	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
10	SA-24-03-25-829	DxC 500i Clinical Analyzer	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
11	SA-25-03-25-830	ABL800 Basic and ABL8XX FLEX analyzers	Radiometer Medical ApS	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov	In vitro diagnostic devices
12	SA-20-10-24-633	Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	Baxter AG	https://ade.sfda.gov	Single-use devices
13	SA-08-01-24-242	MR systems with 60cm wide bore	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices