

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference:

WU2629

الرقم المرجعي للتقرير:

Publish date:

12-Jul-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 05-Jul-26

من

To 11-Jul-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-02-07-26-1453	T-RAC II Terumo Recording and Automatic Blood Collector	TerumoBCT	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
2	SA-06-07-26-1456	AirSeal Access Ports	ConMed Corporation...	Cure Development International Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
3	SA-08-07-26-1459	HOTLINE™ Fluid Warming Sets	Smiths Medical ASD, Inc.	almadar medical Est.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
4	SA-05-07-26-1455	GETINGE Drying Cabinet S-363	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
5	SA-05-07-26-1454	Getinge Flow Family Anesthesia Machines	Getinge Lancer	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
6	SA-06-07-26-1457	Cardiac Workstation 5000 and 7000	Philips Medizin Systeme GmbH	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
7	SA-08-07-26-1458	Sfera hybrid 30.5 calcium hydroxylapatite.hyaluronicacid 3ml	LOVE COSMEDICAL SRL	ALWAN AL DAWAA FOR TREADING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	Non-active implantable devices
8	SA-02-07-26-1452	Abiomed Impella 14 Fr Introducer Kit, Abiomed Impella 23 Fr Introducer Kit	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-23-08-24-569	Philips Azurion, Allura Xper, Integris and MultiDiagnost Eleva	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/	Diagnostic and therapeutic radiation devices