

Safety Alerts Weekly Update

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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 01-Dec-24
To 07-Dec-24

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=CTLNDA7ARTRDHMA>



* 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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-02-12-24-694	- Tec 6 Plus - Tec 820 ISO - Tec 820 SEV - Tec 850 ISO - Tec 850 SEV	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/205	Anaesthetic and respiratory devices
2	SA-28-11-24-692	AT 030 (for SL 800)	Carl Zeiss Meditec Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	Diagnostic and therapeutic radiation devices
3	SA-02-12-24-697	Atellica IM Total Triiodothyronine	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	In vitro diagnostic devices
4	SA-01-12-24-693	Carestation 620/650/650c (with software version 02SP02,02SP03,02SP04 or 02SP05)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	Anaesthetic and respiratory devices
5	SA-11-08-24-550	Centricity PACS 4.0	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	Medical software
6	SA-08-07-24-500	HeartStart Intrepid	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	Electro mechanical medical devices
7	SA-28-11-24-691	IMMULITE 2000 PSA	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	https://ade.sfda.gov.sa/Fsca/PublishDetails/202	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-02-12-24-696	Optima XR200/220/240amx	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
9	SA-25-11-24-687	REACH - Magnum Stapler	Reach Surgical INC.	International Medical Supplies Company	https://ade.sfda.gov.sa/Fsca/PublishD	Reusable devices
10	SA-03-12-24-698	Various procedure packs containing the Codman Surgical Patties	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices