

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2633
Publish date: 09-Aug-26

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 02-Aug-26
To 08-Aug-26

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=7KN979YXNHPPRENX>



* 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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-05-08-26-1498	DISPOSABLE SURGICAL GOWNS	Anhui MedPurest Medical Technology Co., Ltd	Universal Trading and Information Technology	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
2	SA-02-08-26-1490	Hoffmann® II Carbon Connecting Rod	Stryker Communications.....	Zimmo Trading Establishment.	https://ade.sfda.gov.sa/Fsca/PublishD	Reusable devices
3	SA-02-08-26-1489	Centricity Enterprise Archive, Enterprise Archive, Centricity PACS, and Centricity PACS Server	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
4	SA-03-08-26-1493	Aisys CS2, Aisys CS2 with Et Control and S/5 Aisys Anesthesia Delivery Systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
5	SA-03-08-26-1495	ROTOFIX 32 A	Andreas Hettich GmbH & Co. KG	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-30-07-26-1488	GEM PAKs (Cartridges) for GEM Premier 5000 with iQM2®	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-04-08-26-1496	Glycated Hemoglobin Analyzer	Goldsite Diagnostics Inc.	Techno-Orbits Establishment	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
8	SA-02-08-26-1491	Carescape™ Central Station (CSCS) V3.0.x	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Healthcare facility products and adaptations

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-03-08-26-1492	cobas t 511 / t 711 coagulation analyzer	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov	In vitro diagnostic devices
10	SA-03-08-26-1494	Philips Patient Information Center iX (PIC iX) 4.x systems	Philips Medizin Systeme GmbH	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Electro mechanical medical devices
11	SA-28-07-26-1483	Disposable Hemoperfusion Cartridge (HA Series)	Jafron Biomedical Co.,Ltd.	Ayar plus Establishment Medical	https://ade.sfda.gov	Single-use devices
12	SA-30-07-26-1487	Philips Incisive CT System	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices