

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Medical Devices Sector
Surveillance and Biometrics Executive Department

Safety Alerts Weekly Update

24-Dec-23

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 17-Dec-23 من
To 23-Dec-23 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=LK7JLRD397T7DFFR>



* 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 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 الطراز او الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

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-14-12-23-209	Alinity i HBsAg Reagent Kit	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
2	SA-10-12-23-196	Atellica IM FBHCG Atellica IM FBHCG	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	In vitro diagnostic devices
3	SA-18-12-23-216	BrightView, BrightView X, BrightView XCT	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
4	SA-19-12-23-220	CooperSurgical LifeGlobal global Media	CooperSurgical, Inc...	GT Medical	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
5	SA-19-12-23-219	COPPER (Cu)	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
6	SA-11-12-23-202	Dimension IRON	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
7	SA-11-12-23-200	FlexSys	GME German Medical Engineering GmbH	COMPANY QUMA ALJAMAL MEDICAL	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
8	SA-17-12-23-211	HemosIL® AcuStar ADAMTS13 Activity	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-17-12-23-210	Monolisa HCV Ag/Ab ULTRA V2	Bio Rad.	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
10	SA-20-12-23-222	OPTEASE™ Retrievable Vena Cava Filter OPTEASE™ Retrieval Catheter	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
11	SA-17-12-23-213	POLYFILM	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
12	SA-18-12-23-217	RX Daytona Plus (with ISE/without ISE)	Radox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
13	SA-19-12-23-221	Synergy Cranial (9733763) and StealthStation Cranial (9735585)	Medtronic Navigation, Inc.	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices