

Kingdom of Saudi Arabia Saudi Food & Drug Authority



المملكة العربية السعودية الهيئة العامة للغذاء والدواء

Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

05-Nov-23

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

مرفق فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

From 29-Oct-23 من
To 04-Nov-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.

* Role of contact officer:

* مسؤولية ضابط الاتصال:

*** Kindly respond to the weekly report in both cases either you are affected or not affected.**

*** نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر.**

- 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

- 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.

Name of Healthcare Facility

اسم مقدم الرعاية الصحية:

Date:

التاريخ:

Facility affected by any device/product in this report:

يوجد أجهزة/مستلزمات متأثرة في المنشأة ضمن القائمة:

Yes

نعم

No

لا

- The yellow highlights indicates that medical devices subject to removal action.
- To identify the affected serial numbers/lots, please open the link.

- الإجراءات المظللة بالأصفر تشير إلى إجراء سحب الجهاز الطبي.
- لمعرفة الطراز أو الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Safety Alerts: 18 عدد إنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
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Diagnostic and therapeutic radiation devices

Allura Xper, Allura Centron, and Azurion systems.	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda	
BRONCHOVIDEOSCOPE OLYMPUS	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda	
Change Healthcare Radiology Solutions	Change Healthcare	Bio Standards	https://ncmdr.sfda	
Elekta Medical Linear Accelerator	Elekta Inc	Medical Regulations Gate	https://ncmdr.sfda	
MultiDiagnost Eleva with Flat Detector	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda	

Electro mechanical medical devices

Cardiohelp-i	MAQUET Cardiopulmonary Gm	Medical Elements	https://ncmdr.sfda	
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda	
OR Light Systems	MAQUET Inc	Gulf Medical Co.	https://ncmdr.sfda	

In vitro diagnostic devices

K (Potassium) ELECTRODE for AU/DxC AU Beckman Coulter analyzers (AU480, AU680, AU5800 and DxC 700 AU)	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp?caid=4&rid=197	
LIAISON® Chlamydia trachomatis IgG	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda	

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
Nova Biomedical Stat Profile Prime Plus Analyser	Nova Biomedical Corporation	REDWAN MEDICAL SERVICES	https://ncmdr.sfda	
Total Bilirubin Vattadate Gxidation Methed	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda	
Validity Control 3	UTAK Laboratories, Inc.	Farabi Trading Establishment	https://ncmdr.sfda/Secure/CA/CaViewRecall.asp	
Validity Control 3	UTAK Laboratories, Inc.	Farabi Trading Establishment	https://ncmdr.sfda/Secure/CA/CaViewRecall.asp	

Ophthalmic and optical devices

Microscalpel Plastic Handle, Incision Knife	FEATHER SAFETY RAZOR CO., LTD.	Bio Standards	https://ncmdr.sfda	
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Single-use devices

HONEYGO Micro-enema - Easylax Enema- Isipeg suppositories- Redulex baby suppositories	New.Fa.Dem. Srl	Different Concept Company for Trading	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	
Tracheostomy Care and Cleaning Trays	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda	