

Safety Alerts Weekly Update

01-Oct-23

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

مرفق فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 17-Sep-23 من
To 30-Sep-23 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمناثرة 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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات 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: 21 عدد إنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
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Anaesthetic and respiratory devices

Astral 100/150 ventilator	ResMed Limited.	Bio Standards	ecure/CA/CaViewRe	
Disposable breathing circuits for MEDUMAT Transport	Weinmann.	Al Khateeb United Trading Est.	https://ncmdr.sfda	

Diagnostic and therapeutic radiation devices

Luminos Agile Max, Axiom Luminos dRF, Luminos dRF Max, Ysio, Ysio Max, Ysio X.pree with BABIX holder on the Bucky wall stand	Siemens Healthcare GmbH	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=1970	
Membrane Changer Single-Use	SenTec AG.	Medical regulations gate	https://ncmdr.sfda	

Electro mechanical medical devices

F2-01 Frame used with compatible GE multiparameter patient monitors	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
PROVEO 8, M530 OHX and PROvido	Leica Microsystems (Schweiz) AG	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda	
Venue Go Standard Cart	GE Healthcare	GE Healthcare	ecure/CA/CaViewRe	

In vitro diagnostic devices

Accu-Chek Solo diabetes manager	Roche Diabetes Care GmbH	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda	
HemosIL von Willebrand Factor Antigen	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda	
Human Assayed Multi-Sera Control Level 3	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda	

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
Immunoassay Speciality I Level 1. An in vitro diagnostic medical device (IVD)	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
MicroINR easy control	iLine Microsystems S.L	LLA FOUAD HOLDING COM	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Multichem S Plus (Level 1, Level 2, Level 3), Multichem IA Plus, Multichem P	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/	
Randox Liquid Protein Calibrators-SP CAL-(LIQ)	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Randox Urine Liquid Control Level 2	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
RX Daytona Plus (with ISE), RX Daytona Plus (without ISE), RX Imola, RX Modena, RX Monaco	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
VENTANA anti-ALK (D5F3) Rabbit Monoclonal Primary Antibody	Roche Diagnostics GmbH	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	

Ophthalmic and optical devices

Alcon Phaco Tips and packs or kits containing	Alcon Laboratories Inc....	Alcon Pharmaceuticals Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
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Single-use devices

ARW Alcohol Prep Pads	ARW Manufacturing Company	ARW Manufacturing Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
HLS & PLS Set.	AQUET Cardiopulmonary Gm	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
HYBRID12D300/ HYBRID12D300 (China)	Balt Extrusion	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	