

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

30-Apr-23

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

مرفق فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

From 09-Apr-23 من  
To 29-Apr-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 إذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إذارات 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: 16 عدد إنذارات السلامة

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

Seattle PAP plus, Neo disposable breathing systems, Coax ventilation hoses, Pediatric disposable breathing systems, r Set2Go & Pack2Go	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=1951">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=1951</a> 1	
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### Assistive products for persons with disability

ICELOCK RATCHET	Ossur	Al Ewan Medical Company	<a href="#">Secure/CA/CaViewRe</a>	
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### Diagnostic and therapeutic radiation devices

Incisive CT System	Philips Healthcare	Philips Healthcare Saudi Arabia	<a href="#">Secure/CA/CaViewRe</a>	
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### Electro mechanical medical devices

Arrow AutoCAT 2 Intra-Aortic Balloon Pump, Arrow AC3 Optimus Intra-Aortic Balloon Pump	Arrow International Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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Impella 5.5 with SmartAssist heart pump	ABIOMED Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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### Hospital hardware

AMSCO 600 EMEA Sterilizer	STERIS Corporation..	Jeel Medical & Trading Co. L	<a href="#">Secure/CA/CaViewRe</a>	
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Reliance® Vision Multi-Chamber Washer/Disinfectant	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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Wip'Anios Excel	ANIOS LABORATOIRES	Spectromed	<a href="#">Secure/CA/CaViewRe</a>	
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### In vitro diagnostic devices

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
ACL ELITE/ELITE PRO HEMOSTASIS TESTING SYSTEMS	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
aPTT Screen cobas t 600T, aPTT Lupus cobas t 600T, aPTT cobas t 600T.	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
Atellica CH 930 Analyzer	ens Healthcare Diagnostics G	DULREHMAN AL GOSAIBI G	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
BENCHMARK ULTRA STAINER MODULE, DISCOVERY ULTRA (RUO).	Roche Diagnostics GmbH	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
RX Monaco	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	

### Single-use devices

Exmoor Plastics Nasal Splints.	Exmoor Plastics Ltd.	min Medical Instruments Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
SOFT DENUATION TIPS AND FOLLICLE PUNCTION SYSTEMS	Reproline medical GmbH	MED MEANS TRADING	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
Synergy Cranial (9733763) and StealthStation Cranial (9735585)	Medtronic Navigation, Inc.	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	