

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

03-Sep-23

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

مرفق فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

From 27-Aug-23 من
To 02-Sep-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 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: 14 عدد إنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
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Active Implantable Devices

HeartWare™ Ventricular Assist Device (HVAD™) System	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	
HeartWare™ Ventricular Assist Device (HVAD™) System	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA	

Anaesthetic and respiratory devices

HAMILTON-C1/T1/MR1 Ventilators	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA	
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Diagnostic and therapeutic radiation devices

Allura Xper, Allura Centron, Azurion and MultiDiagnost-Eleva systems.	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	
Ingenia Ambition X, Ingenia Ambition S	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	
OPMI LUMERA 300	Carl Zeiss Meditec Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	
Radixact™ Treatment Delivery System	Accuray Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	

Electro mechanical medical devices

EXCOR@ Cannulae	Berlin Heart GmbH	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	
Giraffe OmniBed and Giraffe OmniBed Carestation	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA	
Hamilton Medical Ventilators HAMILTON-C1/T1/C2/C3 with Neonatal Option	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
Xper Flex Cardio Device used with the Xper Flex Cardio Physiomonitring System and Philips Hemo System	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=196	

In vitro diagnostic devices

ORTHO Sera Anti-Lea Murine Monoclonal IgM.	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda	
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Medical software

Centricity™ Enterprise Archive	GE Healthcare	GE Healthcare	https://ncmdr.sfda	
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Non-active implantable devices

Guider Softip™ XF Guide Catheter	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda	
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