

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

18-Jun-23

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

مرفق فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

From 11-Jun-23 من
To 17-Jun-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: 17 عدد إنذارات السلامة

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

Corpuls3 Software	medizinische Geräte G. Stern	Al Khateeb United Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

LUMINOS Lotus Max Luminos dRF Max Luminos Agile Max	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA	
Shimadzu X-Ray system - X-Ray tube support, ceiling mounted CH-200/CH-200M	Shimadzu Corporation..	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	
Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA	

Electro mechanical medical devices

da Vinci Xi/X Tip-Up Fenestrated Grasper	Intuitive Surgical Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	
MEGADYNE™ MEGA SOFT™ and MEGA 2000 Reusable Patient Return Electrodes	Megadyne Medical Products Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA	
Olympus HF-Resection Electrode	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA	

Hospital hardware

Power-PRO 2	Stryker	Jeel Medical & Trading Co. L	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
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In vitro diagnostic devices

Medical Device	Manufacturer	Authorized Representative /Importer	Link	Affected Yes/No
Afinion 2 and Alere Afinion 2	Abbott Diagnostic International	supplies & Services Co.Ltd M	cure/CA/CaViewRe	
IL PVP	tion Laboratory SpA, a Werfe	LLA FOUAD HOLDING COM	cure/CA/CaViewRe	
Urea Enzymatic Kinetic Assay	Randox Laboratories Ltd.	Bio Standards	cure/CA/CaViewRe	

Medical software

BD Synapsys	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	cure/CA/CaViewRe	
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Reusable devices

Allen Advance Chest Support with pad	Baxter Healthcare	Baxter AG	https://ncmdr.sfda	
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Single-use devices

Single Use Distal Cover	Olympus	Salehiya Trading Est.	cure/CA/CaViewRe	
Dr.Disinfectant Instrument Transport Gel	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ncmdr.sfda	
Single-Use Packs, FUSION Dual Pump Packs, Veritas Advanced Infusion Packs	Johnson & Johnson Surgical Vision, Inc.	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA	