

Dear,
NCMDR team send a weekly update every week containing the latest Field Safety Corrective Action/Recalls of medical devices/products on SFDA website.

عزيزي،
يقوم المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بإرسال تقرير اسبوعي عن آخر اشعارات إنذارات السلامة / الاستدعاءات للأجهزة والمستلزمات الطبية المنشورة على موقع الهيئة العامة للغذاء والدواء

* Role of NCMDR officer:

* مسؤولية ضابط الاتصال:

- Disseminate and share the information with other Departments within healthcare facility and Ensuring that the healthcare facility is free of any affected device/product.
- Communicate with NCMDR Team and Authorized Representative of the manufacturer if there is any affected device/product.

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.
- التواصل مع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ومع الممثل القانوني للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.


Hospital name:
Date:
Hospital affected by any medical device/product in this report: No Yes


اسم المستشفى:
التاريخ:
يوجد أجهزة متأثرة بالمستشفى ضمن القائمة: لا نعم

- The yellow highlights Indicates that medical devices subject to removal and/ or destroyed action.
- NCMDR Team Recommend ensuring the listed Authorized representative/Distributor in this report as they may differ from the Authorized representative/Distributor you are dealing with
- The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI.
- Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

- الإشعارات المظللة بالأصفر تشير الى سحب او إتلاف جهاز طبي.
- الممثلين القانونيين/الموزعين في هذا التقرير قد يختلفون عن الممثلين القانونيين/الموزعين الذين تتعاملون معهم.
- هذه العلامة (#) في الجهة اليسرى من التقرير تشير إلى ان اشعار انذار السلامة من منظمة (ECRI).
- لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.

NCMDR Weekly Update 22-Jan-19

Dear,
 NCMDR team is pleased to inform you that **29** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **14-Jan-19** to **20-Jan-19** In order to view more details, click the links or attachments 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **29** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **14-Jan-19** إلى **20-Jan-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Anaesthetic and respiratory devices

Suction Catheters, Gastro- enteral Tubes	ConvaTec	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Dental devices

Orthoplast 910 Violet (1L)	Vertex-Dental B.V.	Medical & Pharmaceutical Services Bashir Shakib Al Jabri	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

ARIA Oncology Information System for Radiation Oncology	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13745	
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Elekta Unity	Elekta Inc	Medical Regulations Gate	/Secure/CA/CaViewRecal	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Swissray ddRCombi Trauma	Swissray	Saudi Health Services Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	


Electro mechanical medical devices

Arrow CVC	Arrow International Inc	Gulf Medical Co.	/Secure/CA/CaViewRecal	
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# Capri Applicators	Varian Medical Systems	medical Systems Arabia Commercial		
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# DIANEAL Low Calcium 2 L/2 L Peritoneal Dialysis Solution with 1.5% Dextrose in 2,000 mL UltraBag Container Bags	Baxter Healthcare	Baxter AG		
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monopolar electrode handles smartPen for active electrodes with 2.4 mm attachment	Gebrueder Martin GmbH & Co KG ,	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13758	
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# Schiller PB-1000 Monitor Units Used with Horizon and McKesson Cardiology Hemo Systems	Change Healthcare	Bio Standards		
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Hospital hardware

# AVE 2 Birthing Beds	Linnet spol. s r.o.	Salehiya Trading Est.		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Eleganza 2	Linnet spol. s r.o.	Salehiya Trading Est.	/Secure/CA/CaViewRecal	

In vitro diagnostic devices

cobas t 511 and t 711 - Coagulation analyzer	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	
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DELFLIA / AutoDELFLIA hCG Kit	PerkinElmer Life and Analytical Sciences	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Oxoid M.I.C.E Meropenem MA0121	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Panocell-16 Kit	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa	
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Quo-Test A1C Test Kit	EKF DIAGNOSTIC GmbH	GAMSCO (General Analysis for Medical Services Company)	https://ncmdr.sfda.gov.sa	
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Non-active implantable devices

Allofit Alloclassic Screw Plug	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa	
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Biomet DVR Crosslock Screws	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa	
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JOURNEY DCF AP Femoral Cutting Block Size 3	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
SL PLUS MIA DOUBLE OFFSET ADAPTER	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	


Ophthalmic and optical devices


VISULENS 500	Carl Zeiss Meditec Inc	Gulf Medical Co.	/Secure/CA/CaViewRecal	
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Reusable devices

# Model 9602 Surgical Clippers by Remington	3M Health Care Ltd	3M company		
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Single-use devices

# ChemoLock Vial Spikes	ICU Medical, Inc	AL-KAMAL Import		
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# LarySeal Laryngeal Mask Airways	FLEXICARE MEDICAL LIMITED	Arabian Health Care Supply Co. (AHCSC)		
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MEDRX POLYURETHANE FEEDING TUBE	Canadian Hospital Specialties	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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NIM Eclipse System, Single Use Direct Nerve Probes	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13	
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Presource Kit Total Joint Pack	Cardinal-Health	MEDICARE DRUG STORE COMPANY	https://ncmdr.sfda.gov.s	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
SYMMETRY OLSEN® SINGLE- USE ELECTROCAUTERY FORCEPS / PENCILS / CORDS	Cooper Surgical, Inc.	Cure Development International Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13761	