

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 21-May-19

Dear,
 NCMDR team is pleased to inform you that **31** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **13-May-19** to **16-May-19** In order to view more details, click the links or attachments 


عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **31** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **13-May-19** الى **16-May-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Active Implantable Devices

WiSE CRT Electrode and Delivery Catheter	EBR Systems, INC	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Assistive products for persons with disability

# Size 3 Wombat Living Assistive Ergonomic Chairs	Etac	Medicare Center		
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Dental devices


emImplant ø 2.0mm, L 12.0mm, Ti	Institut Straumann	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Cios Alpha.	Siemens Medical Solutions	Siemens Medical Solutions		
CT, PET-CT, and SPECT-CT Scanners	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Discovery PET/CT 610, 710, Optima PET/CT 560, 560FX, Discovery IQ, and Discovery MI, MI DR	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14283	
The Infinity M300+	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	



Electro mechanical medical devices

CAIMAN DISP.INSTR.ARTICULAT.D:12/240MM /440MM	Aesculap	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
ECG trunk cables and leadwires	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
IntelliVue MX40 Monitors	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
IRATHERM1000 with IRAcom transducer	VON ARDENNE GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Medtronic HeartWare Monitor AC Adapter ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
Pentax Medical C2 CryoBalloon	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
# Various Precision and Vercise Adapters, Leads, Lead Extensions, and Kits	Boston Scientific Corporation..	Medical Technology Trading Company		
VENTICA skin electrode	Icare Finland Oy	Albasar For Medical Supplies	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

In vitro diagnostic devices


cobas c 311/501/502/701/702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
cobas c 311/501/502/701/702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
Creatine Kinase on the ADVIA Chemistry platform	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14302	
Creatine Kinase on the Atellica Chemistry platform	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
GNR PNA FISH Control Slide kit CS01110	OpGen Inc.	Fawaz Abdulrahman Linjawi Establishment for Medical Equipments & Tools	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
# Platelet PGD Tests	Max Biomedical Incorpora	Delta Specialized Medical Compan		
# RNeasy DSP FFPE Kits	QIAGEN Ltd	ABDULLA FOUAD HOLDING COMPANY	Please check email	
STA-NeoPTimal 20 with STA-Compact/STA-Compact Max	Diagnostica Stago	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
# Various Point-of-Care Handheld Systems	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY		



Non-active implantable devices

Leyla Flexible Arms	LAWTON GmbH & Co., KG	Isam Economic Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
TAPES endoscopic suturing device	Endo Tools Therapeutics SA	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	

Reusable devices

# Prestrol Suction Catheters.	Pennine Healthcare	MEDICARE DRUG STORE COMPANY		
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Single-use devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Endotrac Hook/Triangle Blade Kits	Stryker Endoscopy	Al-Faisaliah Medical System		
# Ethicon ETHIBOND EXCEL Polyester Sutures	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited		
Mobile SL, Ch 12, Ch 14, Ergothan	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.s	
Swan-Ganz Thermodilution Catheter Double Lumen	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCC)	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	