

NCMDR Weekly Update
19-Feb-19

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

عزيمي،
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 المظلمة 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 19-Feb-19

Dear, NCMDR team is pleased to inform you that **38** new FSCA/recalls for medical devices and products posted on SFDA website for the period of 11-Feb-19 to 17-Feb-19 In order to view more details, click the links or attachments 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **38** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 11-Feb-19 إلى 17-Feb-19 ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

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

VALITUDE CRT-P, ALTRUA 2 Pacemaker, ESSENTIO Pacemaker, ACCOLADE Pacemaker, PROPONENT Pacemaker , VISIONIST CRT-P	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13868	
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VALITUDE CRT-P, MOMENTUM CRT-D, AUTOGEN CRT-D , INOGEN CRT-D, VISIONIST CRT-P, VIGILANT CRT-D, CHARISMA CRT- D, DYNAGEN CRT- D, ORIGEN CRT- D, RESONATE CRT-D	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13870	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Anaesthetic and respiratory devices

R100 Patient Set	Metran	LEADER HEALTHCARE SAUDI ARABIA	/Secure/CA/CaViewRecal	
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Dental devices

Henry Schein CU-1000 Halogen Light	Henry Schein, Inc..	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

ARIA OIS for Radiation Oncology	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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# FDR Go Plus Portable Digital Radiography Systems	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY		
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# MAGNETOM Prisma and Prisma Fit Magnetic Resonance Systems	SIEMENS	Siemens Medical Solutions		
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Monaco RTP System	Elekta Inc	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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NeuViz 128 Multislice CT Scanner System	Neusoft Medical Systems	Al Afandi Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
PROGNOST ES / PROGNOST FS / PROGNOST S / PROVERT	PROTEC GmbH & Co. KG	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	
Radimetrics CDM Software ,	Medrad Inc	Scientific & Medical Equipment House	https://ncmdr.sfda.gov.sa	

Electro mechanical medical devices

#	Infinity Delta Family Patient Monitor Software	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.		
	Cordis Vista Brite Tip® & ADROIT Guiding Catheters	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	
	GRP Handles.	oskopische Gerate Gml	Alnawras Global Healthcare	/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	
#	HORIZON E-z Arms Used with HORIZON E-z Cool Coils	The Magstim Company Limited	ATTIEH MEDICO LTD		
	Panda iRes Warmer with ResusView Heart Rate Feature	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
	Vial2Bag Direct Connect 13 mm IV Fluid Transfer Sets	West Pharma Services IL	pharmaceutical solutions industry	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	

Healthcare facility products and adaptations

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
# Foam and Gel Hand Sanitizers	Ecolab Inc	Al Hammadmedical Services		

Hospital hardware

Agila/Movita ceiling supply unit	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.s	
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ATLAS Loading Car	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.s	
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In vitro diagnostic devices


Alinity hq Analyzer	Abbott	cal supplies & Services Co.Ltd Mec	/Secure/CA/CAViewRecal	
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BM-Lactate, LACT Accutrend Plus system	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s/Secure/CA/CAViewRec	
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cobas p 612 pre-analytical system	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s	
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Immunomat Instrument	Institut Virion/ Serion GmbH	Bayouni Trading Co. Ltd	https://ncmdr.sfda.gov.s	
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IMTEC-dsDNA-Antibody	HUMAN Gesellschaft für Biochemica und	Arabian Trade House Est.	https://ncmdr.sfda.gov.s	
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# Piccolo XPress Blood Chemistry Analyzer- Comprehensive Metabolic Panels	Abbott	Medical supplies & Services Co.Ltd Mediserv		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
STA – VWF:RCo reagent .	Diagnostica Stago	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
TGS TA EBV CS	Technogenetics s.r.l.	N/A	/Secure/CA/CAViewRecal	
Various Immunoassay Controls used with Siemens Immulite 2000 .	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.s/a/Secure/CA/CAViewRecall.aspx?caid=10&rid=13881	

Non-active implantable devices

Cortical Screw 3.5	aap Implantate AG.	ture Development International Lt	/Secure/CA/CAViewRecal	
Bonalive putty MIS, System pack and Single pack	BONALIVE BIOMATERIALS LTD.	husn al Emirat Est.	https://ncmdr.sfda.gov.s/a/Secure/CA/CAViewRec	
Hemospray Endoscopic Hernostat	Cook Medical Europe Limited,	ARABIAN MEDICAL & PHARMACEUTICAL CO.	https://ncmdr.sfda.gov.s/a/Secure/CA/CAViewRec	
Motec Wrist Radius Cup	Swemac Innovation AB	N/A	https://ncmdr.sfda.gov.s	
Padlock Clip defect closure system	United States Endoscopy Group, Inc.	ProMedEx	https://ncmdr.sfda.gov.s/a/Secure/CA/CAViewRec	

Ophthalmic and optical devices


Specular Microscope CEM 530	Nidek Co. Ltd.	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.s/a/Secure/CA/CAViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Single-use devices

Bone marrow needle	Argon Medical Devices Inc	Alhaya medical co.	https://ncmdr.sfda.gov.s	
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SAPPHIRE IV administration sets	ICU Medical, Inc	AL-KAMAL Import	https://ncmdr.sfda.gov.s/Secure/CA/CAViewRec	
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# Suction Canister Semi-Rigid Liners/Lids	Medline Industries Inc....	Ikar Establishment		
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