

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 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

18-Dec-18

Dear,
NCMDR team is pleased to inform you that 40 new FSCA/recalls for medical devices and products posted on SFDA website for the period of 10-Dec-18 to 16-Dec-18 In order to view more details, click the links or attachments 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر 40 إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 10-Dec-18 الى 16-Dec-18 ، 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

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=13620	
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Anaesthetic and respiratory devices

fabian Therapy evolution / fabian +nCPAP evolution	Acutronic Medical Systems AG.	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13620	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
TEXAS Bronchoscope Tube	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Assistive products for persons with disability

Flite Clip Sling, 4 Point	Arjo Inc	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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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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InterActive Precision IO Scan Adapter	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

Biograph Horizon's Oversized CT Circuit Breaker	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	
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Digital Angiography System Trinias	Shimadzu Medical Systems.	Al Afandi Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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# Discovery NM 530c and Ventri Nuclear Medicine Systems	GE Healthcare	GE Healthcare		
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IntelliVue MX40 Patient Monitor	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
MOSAIQ Radiation Oncology	Elekta Business Area Software Systems IMPAC Medical Systems Inc.	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
MOSAIQ release version 2.64 SP9 and higher	Elekta Inc	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
SENSIS Vibe Combo	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
# Various Biograph Systems Using CARE Dose4D Algorithms.	SIEMENS	Siemens Medical Solutions		
X1 scanner	3Shape Medical A/S	Bio Standards	/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	

Electro mechanical medical devices

Medtronic HeartWare HVAD System Battery Charger	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
PROXIMATE Hemorrhoidal Circular Stapler	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
Spectra Optia® Apheresis System	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
Trima Accel® Automated Blood Collection System	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Hospital hardware

Blue Flyer Compact hoists	Nausicaa Medical S.A.S	United Medical services Co	https://ncmdr.sfda.gov.s	
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In vitro diagnostic devices


ADVIA Centaur Anti-Thyroglobulin (aTG) Positive Bias, ADVIA Centaur, XP, XPT and CP	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=13590	
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AIA360	Tosoh Corporation	DULLA FOUAD HOLDING COMPA	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecal	
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Atellica IM Anti-Thyroglobulin (aTG) Positive Bias	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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Cisbio - Chromogranin A (CGA-ELISA).	Cis Bio International	N/A	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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# LinkSeq Typing Kits	Linkage Biosciences Inc.	Farabi Trading Establishment		
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# MALDI Biotyper Bacterial Test Standards Kits	Bruker Corp	Gulf Scientific Company. For Laboratories (GSL)		
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Laboratory equipment

CP3000 w/ CTS and w/o CTS 230V	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Non-active implantable devices

Comprehensive Mini Stem, Orthopedic Salvage System (OSS)	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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Biomet 20mm Compress Device Short Anchor Plug With Drill Set	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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Curavisc, Hyaluronic Acid 1%	curasan AG	Sehhatak Aghla Medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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# MAX VPC Tray Base and MAX VPC Screw Caddy Brackets	Zimmer, INC....	Medical Regulations Gate		
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MP Prosthesis stem cementless	Waldemar LINK GmbH & Co	Abdul Jaleel Ibrahim Batterjee Sons Development Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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Single-use devices

# 0.9% Sodium Chloride Injections	Fresenius Kabi AG	Alhaya medical co.		
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Actreen Lite Nelaton	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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DUALSTOP	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	/Secure/CA/CaViewRecall.aspx?caid=2&rid=13611	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# GranuFlo Dry Acid Concentrates	Fresenius Medical Care.	Fresenius Medical Care GmbH		
L25 Needle Guide Bracket	Civco Medical Instruments Inc	Majal Care for Trading Est.	https://ncmdr.sfda.gov.s	
Laser Fiber Assy-Single Use	Leoni Fiber Optics GmbH	N/A	https://ncmdr.sfda.gov.s	
Suction/Anticoagulation Assembly Lines	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
# Various Thermacare Heat Wraps	Pfizer Limited	N/A	