

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

01-Jan-19

Dear,
NCMDR team is pleased to inform you that **45** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **24-Dec-18** to **30-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 **45** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **24-Dec-18** الى **30-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


Platinum ICDs and CRT-Ds	MicroPort CRM S.r.l	Arabian Trade House Est.	https://ncmdr.sfda.gov.s	
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Anaesthetic and respiratory devices

# fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO Ventilators.	Acutronic Medical Systems AG.	Salehiya Trading Est.		
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Oxygen Regulator	eng Medical Equipmen	Al-Asemah Medical Company	/Secure/CA/CAViewRecal	
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Assistive products for persons with disability

# Maxter ENTRAL Side Load Clamps	Maxter Catheters	Reem Alwasat for Trading Company.		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Push Valve / Mag Valve	Otto Bock Healthcare Products GmbH	Al Gaim Comm. Est.	https://ncmdr.sfda.gov.s	

Dental devices

#	Proteus 235 ProteusONE Positioning Systems	Ion Beam Applications S.A.	N/A		
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SiroLaser Blue	DENTSPLY International	Branch of DENTSPLY International I	/Secure/CA/CaViewRecall.aspx?caid=4&rid=13676	
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Diagnostic and therapeutic radiation devices


Centricity Universal Viewer Breast Imaging workflow integration.	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=13676	
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KDR UArm, Bucky and Tubestand	KONICA MINOLTA, INC	Ahmed Abdulwahed Trading Co	https://ncmdr.sfda.gov.s	
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Philips Efficia CM Monitors	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.s	
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Electro mechanical medical devices

CARDIOVIT MS- 2007; MS-2010; MS-2015	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=13676	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Covidien Emprint Standard Percutaneous Antenna with Thermosphere Technology	Covidien LLC...	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13679	
da Vinci Harmonic ACE for use with your da Vinci S and Si systems	Intuitive Surgical Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13671	
# Epix Electrosurgical Probes with Smoke Evacuation and Angled L-Hook Tip	Applied Medical Resources	Dawha Medical		
MiniMed Mio Advance Infusion Set	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13679	
Surgical Microscope Leica M220 F12	Leica Microsystems Inc.	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13679	

Healthcare facility products and adaptations

Bayer Overhead Counterpoise mounting system	Medrad Inc	Scientific & Medical Equipment House	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13679	
GETINGE XS32 Flat Screen Holder	Getinge Disinfection AB	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13679	

In vitro diagnostic devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Alinity i Processing Module.	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Autostainer Slide Racks	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Dimension Vista Intelligent Lab Systems using a Progard Pretreatment Pack on the onboard Millipore Water Purification Module (WPM)	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13675	
GloCyte Automated Cell Counter System GloCyte Low and High Level Controls	Advanced Instruments Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13682	
Liquid Protein Calibrators	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Power Supply Unit for external Barcode Printer in combination with cobas 8100	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13691	
Tosoh AIA Packs	Tosoh Corporation	DULLA FOUAD HOLDING COMPA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
VITEK 2 & VITEK 2 Compact	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
VITROS Chemistry Products VALP Reagent Pack	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	

VITROS® 5,1 FS Chemistry System, Version 3.1	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
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Non-active implantable devices

Allergan Textured Breast Implants and Tissue Expanders	Allergan services international Limited	Cigalah Group	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13	
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BIOLOX delta - cup insert Ø 36/44 mm	Implantcast	AlMafsal Medical Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13	
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# Elixir Filler Kits	Illurion technologies inc	Ideal Life Trading Establishment		
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HydroSet XT Injectable HA Bone Cement	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
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Mayfield Skull Clamp	Integra LifeSciences	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
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NeoSpan SuperElastic Compression Staple with Instruments	In2Bones, SAS	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13 695	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Tritanium Posterior Lumbar (PL) cage	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13678	


Ophthalmic and optical devices

enVista One Piece Hydrophobic Acrylic Intraocular lens	Bausch & Lomb GmbH..	Medical regulations gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13678	
neoBLUE blanket LED Phototherapy Systems ,	Natus Medical Inc.	Saudi Health Services Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Reusable devices

AMSCO 3052 and AMSCO 5052 Single-Chamber Washer/Disinfectors equipped with an automated SCS conveyor and barcode system	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13680	
Various Olympus Grasping Forceps and Biopsy Forceps ,	Olympus Winter & IBE GmbH	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Single-use devices

# Cardioplegia Tubing Packs	Medtronic SA	Medtronic Saudi Arabia		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Covidien Parietex Composite Parastomal Mesh	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Empower FastLoad CT Syringe Pack	Bracco Injeneering S.A..	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Entuit Secure Gastrointestinal Suture Anchor Sets	Cook Medical Europe Limited	Majal Care for Trading Est.		
Surdial X	pro Medical Corporatio	Spectromed	/Secure/CA/CaViewRecal	
Theragenics Brachytherapy needles	Theragenics Corporation	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	