



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

25-Dec-18

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 25-Dec-18

Dear, NCMDR team is pleased to inform you that **59** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **17-Dec-18** to **23-Dec-18** In order to view more details, [click the links or attachments](#) 

عزيمي،
يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **59** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **17-Dec-18** الى **23-Dec-18** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

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


#	CareLink 2090, CareLink Encore 29901, and CareLink 9790 Programmers	Medtronic SA	Medtronic Saudi Arabia		
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HeartMate 3 Left Ventricular Assist System.	Abbott Cardiovascular and Neuromodulation	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13627	
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Anaesthetic and respiratory devices

fabian HFO, fabian +nCPAP evolution and fabian Therapy evolution	Acutronic Medical Systems AG.	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13627	
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Assistive products for persons with disability


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# CAPS II and MiniCAPS Seating Systems	Active Design Ltd	N/A		

# Minstrel Passive Floor Lifts without Scales ,	Arjo Huntleigh	Al-Faisaliah Medical System		
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Diagnostic and therapeutic radiation devices

AngelSounds JPD-100S4 Fetal Doppler	Shenzhen Jumper Medical Equipment Co., Ltd.	Leader Specialized Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Biograph Horizon ,	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa	
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# Ingenia Elition S and Ingenia Elition X Magnetic Resonance Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		
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Intera, Omniva, Enterprise, Achieva, Achieva XR, Achieva Conversion, Panorama HFO, Ingenia, SmartPath to dStream, Multiva, Prodiva, MR OR, MR-RT, MR-Linac, MR-Marlin systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13664	
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Nicolet EEG Wireless Amplifier	Natus Neurology	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# StealthAir Percutaneous Pin Adapters	Medtronic SA	Medtronic Saudi Arabia		
Various Endoscopes ,	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.s	

Electro mechanical medical devices

Billed Maxi+ Phototherapy Unit	Novos Medical Systems Industry	N/A	https://ncmdr.sfda.gov.s	
CARESCAPE ONE / CARESCAPE B850 ,	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
# da Vinci Xi/X EndoWrist Monopolar Curved Scissors	Intuitive Surgical Inc	Gulf Medical Co.		
# EDS Light Suspension Central Axis Component of Visum LED Surgical Lighting Systems ,	Stryker Communications	Al-Faisaliah Medical System		
# Medtronic MiniMed 640G Insulin Pump.	Medtronic SA	Medtronic Saudi Arabia		
# MiniMed 630G and 670G Insulin Pumps	Medtronic SA	Medtronic Saudi Arabia		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
multiFiltratePRO device (M205001)	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ncmdr.sfda.gov.s	
Navilyst Medical BioFlo PICC with ENDEXO and PASV	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
Stryker Visum II LED Surgical Lighting system - EDS (Equipment Delivery System) Light Suspensions, Central Axis	Stryker Communications	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=10&rid=13659	
VACUUM CONTROL VALVE	CAIR LGL	Arabian Trade House Est.	https://ncmdr.sfda.gov.s	

Healthcare facility products and adaptations

#	Lap Sponges	Medline Industries Inc...	Spectromed		
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Hospital hardware

Steelco DS1000 washers ,	Steelco SpA.	Insight Medical Systems	https://ncmdr.sfda.gov.s	
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In vitro diagnostic devices

AIA2000 and AIA900 Analyzers	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.s	
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AIA360 Analyzer	Tosoh Corporation	DULLA FOUAD HOLDING COMPA	/Secure/CA/CaViewRecal	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
AIA900 Automated Immunoassay Analyzer.	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
ARCHITECT B12 Reagent Kit ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
ARCHITECT Rubella IgM Reagent Kit ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
# BenchMark ULTRA and DISCOVERY ULTRA Systems with Ventana System Software	Roche Diagnostics GmbH	Al-Jeel Medical & Trading Co. LTD		
BRILLIANCE ESBL / BRILLIANCE CRE BIPLATE	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
Calcium assay on RX instruments	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
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=13665	
Fructosamine Calibrators and Controls	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	



MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
MAS Alcohol/Ammonia Control ,	Microgenics Corp.	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
PP2001 HBA Agar Plates	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
TODA AMNIODIAG 5 strip and TODA AMNIODIAG 5 cassette	TODA PHARMA	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13629	
UniCel Dxl 600 & 800 Access Immunoassay Systems & UniCel DxC 660i, 680i, 860i, 880i Synchron Access Clinical Systems .	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=13657	

Laboratory equipment

i-STAT CG8+ Cartridges	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Non-active implantable devices

Anatomic Tibial Base Plate for fixed bearing insert cemented, Size 4	Amplitude GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=13656	
Ceramic femoral heads and Ceramic cup inserts	OHST Medizintechnik AG	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13	

	MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
#	Various Compress and Mini Compress Devices and Instruments	Zimmer, INC....	Medical Regulations Gate		
#	ViaCell Allografts	Globus Medical, Inc	ProMedEx		



Ophthalmic and optical devices



	RayOne Trifocal RAO603F + 10.5 D ADD 3.5 Intraocular Lens	Rayner Intraocular Lenses Limited	Mohamed Abdul Latif Basha Medical Services L.L.C	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
	VisuMax 2.10.13	Carl Zeiss Meditec Inc	Gulf Medical Co.	/Secure/CA/CaViewRecal	

Reusable devices

	CORAIL Female Broaches (Size 9-20)	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Single-use devices

#	0.9% Sodium Chloride Injections	Fresenius Kabi AG	Alhaya medical co.		
#	Arrow PICC Powered by Arrow VPS Precision Stylet Kits	Teleflex Medical..	Gulf Medical Co.		
	BD Burette Sets	Becton, Dickinson And Company	Medical Regulations Gate	https://ncmdr.sfda.gov.s	

	MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
#	Breast Milk Transfer Lids	Medela Inc	batterjee medical services		
#	Cardinal Health DERMACEA and KERLIX Bandage and Gauze Rolls	Cardinal-Health	MEDICARE DRUG STORE COMPANY		
	Celsite Safety SST601F 6.5F SI - Access Ports	B. Braun Melsungen	ProMedEx	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
	DUALSTOP	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	/Secure/CA/CaViewRecal	
#	Dyural-40 and Dyural-80 Convenience Kits	Asclemed	N/A		
#	Ecolab Enzymatic Detergents	Ecolab Inc	Al Hammadmedical Services		
	ExactaMix	Diffuplast sri	Baxter AG	/Secure/CA/CaViewRecal	
	Mako Vizadiscs and Vizadisc Hip Tracking Kit	MAKO Surgical Corp	Zimmo Trading Establishment.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
#	U by Kotex Sleek Tampons	Kimberly Clark Health Care..	N/A		
#	Various Pre-Connected Foley Tray Systems	C R Bard Inc	C.R. BARD Saudi Arabia		