

NCMDR Weekly Update

02-Jul-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.

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:

*** Kindly respond to the NCMDR weekly report in both cases either you are affected or not affected.**

*** نأمل الرد على تقرير المركز الوطني لبلاغات الاجهزة و المنتجات الطبية في حالتي التأثر أو عدم التأثر.**

- 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:

اسم المستشفى:

Date:

التاريخ:


Hospital affected by any medical device/product in this report: Yes
No


يوجد أجهزة متأثرة بالمستشفى ضمن القائمة: نعم
لا

- 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 02-Jul-19

Dear,
 NCMDR team is pleased to inform you that **41** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **25-Jun-19** to **30-Jun-19** In order to view more details, click the links or attachments 


عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **41** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **25-Jun-19** إلى **30-Jun-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

Ellipse ICD	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	/Secure/CA/CaViewRecal	
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Anaesthetic and respiratory devices

# Maxtec Maxblend Rail Mounts	Tri anim Health Services Inc	N/A		
iGUIDE 2.2 ,	Elekta Limited	Medical Regulations Gate	/Secure/CA/CaViewRecal	

Assistive products for persons with disability



Tenor Passive Floor Lift	Arjo Huntleigh	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.s	
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Dental devices





Titanium abutment cemented GH 5.5 mm	Hager & Meisinger GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
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Diagnostic and therapeutic radiation devices

Elekta Unity..	Elekta Inc	Medical Regulations Gate	/Secure/CA/CaViewRecal	
G4 Platinum System, Dexcom G5 Mobile	DexCom Inc	Bio Standards	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
ICS CHARTR EP 200	GN Otometrics	Gulf Medical Co.	https://ncmdr.sfda.gov.s	



	MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
#	Lead Aprons, Sleeves, and Thyroid Shields	Burlington Medical Supplies Inc	N/A		
#	Various Artis Systems	SIEMENS	Siemens Medical Solutions		

Electro mechanical medical devices

#	Datascope CARDIOSAVE Intra-Aortic Balloon Pumps	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD		
	Datascope CARDIOSAVE Intra-Aortic Balloon Pumps	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
#	Dialog+ Hemodialysis Machines	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv		
	Fisher Scientific Isotemp -General Purpose Water Bath	Thermo Fisher	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
#	LEEP Precision Generators	Cooper Surgical, Inc.	Cure Development International Ltd		
	MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14487	
#	Neutrogena Light Therapy Acne Mask and Refill Activator	Johnson & Johnson Medical GmbH	Johnson & Johnson Medical Saudi Arabia Limited		
	RF electro-surgical unit for arthroscopy	EMED SP. Z O.O. SP. K.	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	

In vitro diagnostic devices

	BILD2 (Bilirubin direct Gen.2) and cobas c 701 / 702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
	Calibrator TruCal U	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
CP3000 w/ CTS 120V, CP3000 w/ CTS 230V, CP3000 w/o CTS 120V, CP3000 w/o CTS 230V	Sekisui Diagnostics	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14480	
Freedom EVO 200	ecan Sales Austria GmbH	Amir Photographic Supplies Co. Ltd	/Secure/CA/CaViewRecal	
MiAG cTnI	Magnisense SE	N/A	/Secure/CA/CaViewRecal	
# OpTmizer CTS T-Cell Expansion Serum-Free Media	Life Technologies Limited.	Integrated Gulfbiosystems		
Presage ST2 Assay	Critical Diagnostics	N/A	/Secure/CA/CaViewRecal	
# Seralite FLC Serum Test Kits	Abingdon Health	Dar Al-Zahrawi Medical Co. LLC		
Stratus CS Acute Care cTnI TestPak	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Tina-quant Myoglobin Gen.2 MYO2	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Non-active implantable devices


Barricaid Prosthesis	Intrinsic Therapeutics Inc.	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.s	
DVR Crosslock ePAK Screw Driver, DVR Crosslock ePAK Depth Gauge, K-Wire Trochar Tip	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14483	
Hancock II T510 Bioprosthesis, Mosaic 310 Bioprosthesis,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
MID-Tube, Orogastric calibration Tube	Medical Innovation Developpement SAS	Lawazim Al Jawdah Medical Supplies Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
orientation guide SYMBOL CUP Instrum, SYMBOL STEM, ADES, SHIVA, TRICCC and SMS Instruments	Dedienne Santé	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14475	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Ophthalmic and optical devices

AEROTube® - LK02-GB-M	HUM GmbH	N/A	https://ncmdr.sfda.gov.s	
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Reusable devices


#	Cartilage Microtome Systems and Cartilage Microtome Replacement Handles	Grace Medical Inc	Mohamed Abdul Latif Basha Medical Services L.L.C		
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DA8K-10-14453 British standard power cord	Shenzhen Mindray Bio-Medical Electronics Co.,Ltd.	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
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Single-use devices

Arterial Catheterization Set	Arrow International Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
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#	GaleMed Babi.Plus 12.5 cm H2O Pressure Relief Manifolds	Teleflex Medical..	Gulf Medical Co.		
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#	NF11 and NF11X NorthFlex Red Gloves	Honeywell	N/A		
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#	Premier Soft Convex CeraPlus Tape-Bordered Barriers	Hollister Inc	FAROUK, MAAMOUN TAMER & COMPANY		
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Vasco-OP Sensitive Gr. 8,5 Sterile.	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
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