



NCMDR

National Center for Medical Devices Reporting
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

05-Jun-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 05-Jun-19

Dear,
 NCMDR team is pleased to inform you that **39** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **27-May-19** to **02-Jun-19** In order to view more details, click the links or attachments 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **39** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **27-May-19** إلى **02-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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Anaesthetic and respiratory devices

#	HAMILTON-G5/ HAMILTON-S1 ventilator unit	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est		
#	Sheridan Endotracheal Tubes	Teleflex Medical..	Gulf Medical Co.		

Assistive products for persons with disability

Tilt & Recline Shower Commode: Aspire, 46cm and 53cm	Aidacare Pty Ltd	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14360	
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Biologically-derived devices

REGENYAL IDEA BODY	REGENYAL Laboratories S.R.L.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14360	
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Dental devices

X-Cid2	MICRO-MEGA S.A	Cigalah Group	/Secure/CA/CaViewRecall.aspx?caid=10&rid=14360	
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Diagnostic and therapeutic radiation devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ARTIS zee and AXIOM Artis systems with generator A100	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
LVivo EF app on Vscan Extend	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
MAGNETOM Vida and Sola with syngo MR XA11 software	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Electro mechanical medical devices


Alaris Pump Module model 8100	Becton, Dickinson And Company	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
McKesson Cardiology Hemo Systems	Change Healthcare	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Hospital hardware

# Anti-Fog Solution	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.		
Oakworks Imaging Tables	Oakworks	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

In vitro diagnostic devices

Alinity i BNP Calibrators and Controls	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14379	
ARCHITECT BNP Calibrators and Controls	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14379	
AssayTip / AssayCup, cobas e 601 module, cobas e 602 module, MODULAR ANALYTICS E combinations, MODULAR ANALYTICS EVO E combinations	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14379	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
BN ProSpec System and Atellica NEPH 630 System	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Chocolate agar + PolyViteX	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
Elecsys Syphilis (200 test/kit), MODULAR ANALYTICS E170, cobas e 411, cobas e 601, cobas e 602	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
EliA RF IgM Well	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
HUMAN ASSAYED MULTI-SERA Level 2	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
IGA-2 (Tina-quant IgA Gen.2), cobas c701/702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
MicroVue C4d Fragment EIA	Quidel Corporation	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
PTS Panels	er Technology Systems	rauf Ibrahim Batterjee & Bros. Cor	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
# Uni-Gold Recombigen HIV-1/2 Assays	Trinity Biotech plc.	AL OSOOL MEDICAL TRADING COMPANY		

Medical software

Guardian Connect CGM System	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
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Non-active implantable devices


Opteform Allograft	Exatech inc.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
# Size 4 Medium Oxford Anatomic Meniscal Bearing ArCom Devices	Zimmer, INC....	Medical Regulations Gate		

Ophthalmic and optical devices



CEM-530 Specular Microscope	Nidek Co. Ltd.	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14377	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Reusable devices

#	4 mm SECURODRAIN and 4 mm NeuroVac Silicone Flat Drains	Neuromedex GmbH	N/A		
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Single-use devices

	EQUISTREAM, EQUISTREAM XK, and GLIDEPATH Long-Term Hemodialysis Catheters	C R Bard Inc	C.R. BARD Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14355	
#	Gillette Daisy Classic and Venus Simply Disposable Razors	Mckesson Information Solutions LLC	N/A		
	Intro-Flex Percutaneous Sheath Introducers	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
#	Intro-Uri-Cath Urethral Catheters	Pennine Healthcare	MEDICARE DRUG STORE COMPANY		
	Nasal Alar SpO2 Sensor	Xhale Assurance, Inc	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
#	QUADROX-i Neonatal Oxygenators	MAQUET Cardiopulmonary GmbH	Medical Elements		
	RUSCH LASERTUBE (Rubber)	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14371	
	Sensation Plus 7.5 Fr. 40cc Intra-Aortic Balloon Catheter with Accessories	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14371	
	ThermaCare Lower Back & Hip Heatwraps	PFIZER CONSUMER HEALTHCARE	Ahmed Mohammed Abdulwahab Naghi & Sons	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
#	Various Products	Pennine Healthcare	MEDICARE DRUG STORE COMPANY	