

NCMDR Weekly Update

25-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.

عزيري،
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 25-Jun-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 **17-Jun-19** to **23-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 **17-Jun-19** إلى **23-Jun-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Anaesthetic and respiratory devices

Hudson RCI Air Cushion Face Mask	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Sheridan Endotracheal Tubes	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Assistive products for persons with disability




Magic mobility wheelchair - Mobility Handles	Magic Mobility	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Diagnostic and therapeutic radiation devices

# Centricity Universal Viewer with Centricity PACS Foundation 6.0 SP9 or Higher	GE Healthcare	GE Healthcare		
Cios Alpha VA20 /VA30 and Cios Fusion systems	Siemens Medical Solutions	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Curve and Kick Systems Using Remote Desktop Services for Microsoft Windows Operating Systems	BrainLAB	Al-Jeel Medical & Trading Co. LTD		


Electro mechanical medical devices

6 Fr Sherpa Active Catheters, 6F Sherpa	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Accu-Chek Insight insulin pump system	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Giraffe Bedded Warmer/Panda iRes Warmer	GE Healthcare	GE Healthcare		
# HeartStart MRx Monitor/Defibrillators	Philips Burton	Philips Healthcare Saudi Arabia Ltd.		
LEEP Precision Integrated System	CooperSurgical Inc..	ATTIEH MEDICO LTD	https://ncmdr.sfda.gov.s	
Philips PageWriter TC Cardiographs (TC20/30/50/70)	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Sinapi Chest Drain	napi Biomedical (Pty) Lt	L Medical Development Foundati	 Attached	
Spectra Optia Apheresis System	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Steam Sterilizer	Skytron LLC	N/A	/Secure/CA/CaViewRecal	
TECOtherm NEO.	TEC COM GmbH.	Techno-Orbits Establishment	/Secure/CA/CaViewRecal	
ZOLL AED PRO Product Family	ZOLL Medical Corp	Arabian Health Care Supply Co. (AHCS)	https://ncmdr.sfda.gov.s	

In vitro diagnostic devices

ACHRAb RIA kits.	RSR Ltd	N/A	Secure/CA/CaViewRecall	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ALT/GPT (IFCC) , LDH (IFCC) , LDH (SCE) , alpha-HBDH , Creatine Kinase (IFCC) , and Glucose (Hexokinase) without sample blank	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14453	
A-LYTE™ Integrated Multisensor (IMT NA K CL), Atellica CH Analyzer ,	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14452	
Aptima Combo 2 Assay	HOLOGIC NV	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14428	
ARCHITECT Ceruloplasmin, Alinity c Ceruloplasmin Reagent Kit ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14428	
Assayed Bovine Multi-Sera - Level 1 .	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	
cobas 6800/8800 Systems ,	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	
DiaClon Rh-Subgroups + K ,	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	
FluoroSoftware IVD used with FluoroCyclers 12 & 96	Hain Lifescience GmbH	Bio Alternatives Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	
IVD, IDKmonitor® Infiximab ,IDKmonitor® Adalimumab, Remsima® Monitor , 25(OH)-Vitamin D direct day ELISA I K 2108 futurelots,	Immundiagnostik AG	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	
Quo-Lab A1C Test Kit / PocketChem HbA1C Test Kit	EKF DIAGNOSTIC GmbH	GAMSCO (General Analysis for Medical Services Company)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14444	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Rx Daytona Plus analyser and RX imola analyser	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
SYNCHRON Systems Phosphorus Reagent (PHOSm) .	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14435	
# Vacutainer Plastic Lithium Heparin Tubes	BD Biosciences	Becton Dickinson B.V.		

Non-active implantable devices

# Comprehensive Reverse Shoulder Instrument Cases	Zimmer, INC....	Medical Regulations Gate	Please check email for PDF file	
iTotal Hip Replacement System ,	ConforMIS	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
The MobiC Cervical Disc Prosthesis (MobiC; MobiC 14mm Distraction Screw	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14463	

Ophthalmic and optical devices

The software of the floor stands FS 2-21, FS 2-25, FS 3-45 in combination with the operating microscope HS Hi-R NEO 900 /A /A NIR	MÖLLER-WEDEL GmbH & Co. KG	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14447	
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Reusable devices

DA8K-10-14453 British standard power cord ,	Shenzhen Mindray Bio-Medical Electronics Co., Ltd..	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
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Single-use devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Ethicon ETHIBOND EXCEL Polyester Sutures	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
Microtainer Tubes	Becton Dickinson & Co. (E	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
Monarch Medical Technologies EndoTool IV	Monarch Medical Technologies	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
No. sterile pin guide	Tornier Inc..	Cure Development International Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
Occlutech Delivery Sets (ODS)	Occlutech Holding AG	Medglories Medical Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	