



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

05-Mar-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.

عزيمي،
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.

• الإشعارات المظللة بالأصفر تشير الى سحب او إتلاف جهاز طبي.

• 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

• الممثلين القانونيين/الموزعين في هذا التقرير قد يختلفون عن الممثلين القانونيين/الموزعين الذين تتعاملون معهم.

• The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI.


• هذه العلامة (#) في الجهة اليسرى من التقرير تشير إلى ان اشعار انذار السلامة من منظمة (ECRI).

• Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

• لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.



NCMDR Weekly Update 05-Mar-19

Dear,
 NCMDR team is pleased to inform you that **57** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **25-Feb-19** to **03-Mar-19** In order to view more details, [click the links or attachments](#) 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **57** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **25-Feb-19** إلى **03-Mar-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

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

#	Emergency Monnal T60 Ventilators	Air Liquide Medical Systems	N/A		
#	eSeries Ventilators	vo Medical Technologie	Dar Al Najat Medical Tech.		
	Septiflow Circuit	TIBBI MALZEME SAN. VI	Kafou Medical Co.,	/Secure/CA/CaViewRecal	

Assistive products for persons with disability

	Otoform Ak soft	Dreve Otoplastik GmbH	ABDULREHMAN AL GOSAIBI GTB	/Secure/CA/CaViewRecal	
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Dental devices


	Zirkon Primer	Dentale Forschung und	N/A	/Secure/CA/CaViewRecal	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Diagnostic and therapeutic radiation devices

Brainlab Spine & Trauma 3D Navigation 1.0	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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BRANSIST safire	rimadzu Medical System	Al Afandi Establishment	/Secure/CA/CaViewRecal	
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# IntelliSpace Cardiovascular and Xcelera Systems.	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		
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LOGIQ P5 Model BT06/BT08 and LOGIQ A5 BT08 systems	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
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MultiDiagnost-Eleva, Urodiagnost, OmniDiagnost-Eleva and OmniDiagnost-Classic	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13954	
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Electro mechanical medical devices

C2 CryoBalloon Ablation System	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa	
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# da Vinci S/Si PK Dissecting Forceps Instruments	Intuitive Surgical Inc	Gulf Medical Co.		
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da Vinci Xi/X Erbe Footswitch User Manual	Intuitive Surgical Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Dialog iQ HD, Dialog iQ HD comfort und Dialog iQ HDF comfort Dialysis Machines	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13952	
# Duo ULT Chlorine Dioxide Cleaning Products	Tristel Solutions Ltd	Bio Standards		
ECG trunk cable	GE Healthcare	GE Healthcare	/Secure/CA/CaViewRecal	
Hermes NC PTA Balloon Dilation Catheter	BrosMed Medical Co.,Ltd.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Terumo Cardiovascular Systems	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Various CARESCAPE, Dash, and Solar Patient Monitors	GE Healthcare	GE Healthcare		

Hospital hardware


FLOATABLE PLASTIC BACK/ SPINAL-BOARD NEPTUNE STRETCHER FOR HORIZONTAL TRANSFER	S.KONSTANTINIDIS & CO LTD	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13943	
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In vitro diagnostic devices

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Aldosterone ALDO-RIACT;T4 OCPG07-T4 and OCPG57-T4; FPSA FPSA-RIACT;PSA PSA-RIACT;Chromogranine A CGA-RIACT; T3 OCPE7-T3 and OCPE57-T3;Chromogranine A CGA-Elisa (Protocole long)	Cisbio Bioassays	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
BD MAX Enteric Bacterial Panel	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
DHEA ELISA	BL International GmbH	Samir Trading and Marketing CJSC	/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
DiaSpect Hemoglobin T-LOW analyzer	EKF DIAGNOSTIC GmbH	GAMSCO (General Analysis for Medical Services Company)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
Enzygnost Syphilis.	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
IDS-iSYS ACTH	Indiagnostic Systems Ltd	Audi Mais Co. For Medical Products	/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
IgG4 Food-Screening – Conjugate Kit	Dr. Fooke-Achterrath Laboratorien GmbH	Arabian Medical and Hospital Supplies Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
Mentype MycoDermQS Lateral Flow.	Biotype Diagnostik GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	
Stratec GEMINI und Stratec GEMINI Combo	STRATEC Biomedical Systems AG	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13926	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
t-PSA Rapid Test / Free PSA Rapid Test	Dongguan Bosh Biotechnologies, Ltd.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
Vitek 2	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	/Secure/CA/CaViewRecall	
# VITEK 2 Gram-Positive AST Test Kits	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD		
VITROS 3600, 5600, and XT 7600 Systems	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
xTAG Gastrointestinal Pathogen Panel (GPP)	Luminex Molecular Diagnostics Inc	Hatem I. Alshedwy Comm. Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13	

Laboratory equipment


# HVN Mech Automation Kits Used with ADVIA Chemistry XPT Systems	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB		
NEOselect, NEOonsite - Data Analysis & NEOdb	New Oncology GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
RegenKit-BCT-3T, RegenKit-BCT-2A, RegenKit-BCT-4	Regen Lab SA	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
UniMatch Plus Software	One Lambda Inc	Farabi Trading Establishment	https://ncmdr.sfda.gov.sa	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Non-active implantable devices

#	28 mm Modular Femoral Heads	Stanmore Implants Worldwide Ltd.	Zimmo Trading Establishment.		
	Biomet Comprehensive Reverse Shoulder	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
	Equinoxe Preserve Humeral Stem, 8mm	Exactech	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
	EVOK femoral stem Standard	Amplitude GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
#	Gentrix Thick Surgical Matrices	ACell Inc	N/A		
	GMK UNI Femur	Medacta International S/	N/A	/Secure/CA/CaViewRecal	
	Günther Tulip®, Cook Celect®, & Cook Celect® Platinum Vena Cava Filter Sets	William Cook Europe ApS	Majal Care for Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13946	
	LifePearl microspheres	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
	SMF Stem With Stiktite	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Single-use devices

	MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
#	ChemoLock Vial Spikes	ICU Medical, Inc	AL-KAMAL Import		
#	EXACTAMIX Empty EVA Bags	Baxter Healthcare	Baxter AG		
	Fiber Plasma Filter, Prismaflex Sets, Evodial Dialyzers and Dialisan Solution	Baxter Healthcare	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=13922	
	GelPOINT Path Transanal Access Platform	Applied Medical Resources	Dawha Medical	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13944	
	Maquet Cardiopulmonary Pre-Bypass Filters used for Customised Tubing Packs ,	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=8&rid=13925	
	Plus 30 PRIORITY PACK (Accessories Kits)	Abbott Vascular	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13944	
	Portex Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes	Smiths Medical International Limited	almadar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=8&rid=13925	
	SmartStitch PerfectPasser Connector	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13944	
	Surgical convenience kits	American Contract Systems, Inc.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13944	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
WEB Detachment Controller	Sequent Medical, Inc.	white iris est	https://ncmdr.sfda.gov.s	