

NCMDR Weekly Update

22-Sep-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 22-Sep-19

Dear,
 NCMDR team is pleased to inform you that **42** new FSQA/recalls for medical devices and products posted on SFDA website for the period of 15-Sep-19 to 19-Sep-19 In order to view more details, click the links or attachments 


عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **42** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 15-Sep-19 إلى 19-Sep-19 ، 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

Adapta Dual Chamber Pacemakers ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Anaesthetic and respiratory devices

# ISO 5.0, Size 00 One-Piece Guedel Blue Airways	Intersurgical Limited	Al Hammad Medical Services		
V60 and V600 Ventilator	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Assistive products for persons with disability

# Knight Scooters	rive DeVilbiss Healthca	DIMENSIONS CONSULTANCY OF		
Shuttle Discovery with 4 Wheel Verve Stroller .	Medifab Medical Fabrication	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Diagnostic and therapeutic radiation devices

Ru-106 Augenapplikatore n	Ecken & Ziegler BEBIG GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
TxRx Knee Coil 1.5T and 3T for Use on Siemens MR Systems	Quality Electrodynamics, LLC (QED)	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	

Electro mechanical medical devices

#	Aquilex Fluid Control Systems	W.O.M. World of Medicine GmbH	Medtronic Saudi Arabia		
	CareLink 2090 and CareLink Encore 29901/29901A Programmers	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14813	
	Cerelink ICP Monitor ,	Johnson & Johnson Medical GmbH	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.s	
	CT900 Clinician Programmer ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.s	
	GentleCool Pro Cryogen Canister ,	Candela Corporation	Imdad Medical Business Company Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
#	Nexframe Stereotactic Systems and O-arm Imaging Systems with StealthStation Auto-Registration Feature	Medtronic SA	Medtronic Saudi Arabia		
#	ROSA Brain 3.0 Surgical Systems	Zimmer, INC....	Medical Regulations Gate		
#	Steam Sterilizer Pressure Transducers	Getinge Sterilization AB	Gulf Medical Co.		
#	Various Flexible Endoscopes	Karl Storz Endoscopy UK Ltd	Gulf Medical Co.		

In vitro diagnostic devices

	Alinity ci-series Level Sensor, Bulk Solution .	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
	Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module .	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14794	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
AQURE system..	Radiometer America Inc	Salehiya Trading Est.	/Secure/CA/CaViewRecal	
Dynex DSX Instrument	Dynex Technologies Ltd	AL-MOHANAD MEDICAL EST	https://ncmdr.sfda.gov.s	
IM Quick Test ,	aft für Biochemica und	Arabian Trade House Est.	/Secure/CA/CaViewRecal	
IMMAGE Total Immunoglobulin E (IgE) Reagent .	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec	
OriGen Products TissueVault O-Wrap and accessories .	OriGen Biomedical	Arabian Trade House Est.	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec all.aspx?caid=10&rid=1	
Reagent CRP FS	s Diagnostic Systems G	ALGhuyum Scientific Trading	/Secure/CA/CaViewRecal	
# STI PLUS ELITE MGB Kits Used with ELITE InGenius Instruments	ELITech Clinical Systems SAS	AL-KAMAL Import		
SYNCHRON Systems Cannabinoid 100 ng (THC) & SYNCHRON Systems Cannabinoid 50 ng (THC5) Reagents ,	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec all.aspx?caid=10&rid=1 4799	
SYNCHRON Systems Opiate 300 ng (OP) Reagent and SYNCHRON Systems Opiate 2000 ng (OP2) Reagent .	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec all.aspx?caid=10&rid=1 4801	
Tina-quant Myoglobin Gen.2 MYO2	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec	

Non-active implantable devices

ADTECH Drill Sleeve Guides	Ad-Tech Medical Instrument Corp	Al-Nozha Medical Est	https://ncmdr.sfda.gov.s	
Medsil Intra-gastric Balloon	JSC "MEDSIL"	MEDICAL INNOVATIONS EST.	https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Vanguard XP-CR Tibial Tray ,	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.s	





Ophthalmic and optical devices

1-DAY ACUVUE MOIST for ASTIGMATISM	Johnson & Johnson Vision Care	Allied Medical International	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
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Reusable devices

SMART DTHC .	Getinge Disinfection AB	Gulf Medical Co.	/Secure/CA/CaViewRecal	
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Single-use devices

# Alpha Conducting Solutions	Electromedical Products International	Dal Pharma		
# Catheter Mounts and Face Mask Kits	Armstrong Medical.	JAMJOOM MEDICAL INDUSTRIES CO. LTD.		
# CirClamp Circumcision Clamps	Centurion Medical Products	Bio Standards		
Introcan Safety IV Catheter	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
Serres Suction Bag Liner .	Serres Oy	Alwan Alnoor Trading Est.	https://ncmdr.sfda.gov.s	
Swan-Lock Needle-Free Connector ,	CODAN Medizinische Geraete GmbH & Co KG	Alwan Alnoor Trading Est.	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
# Vacutainer Push-Button Blood Collection Sets with Pre-Attached Holder	BD Biosciences	Becton Dickinson B.V.		
VHK and VKMO Adult/Small Adult .	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
VHK and VKMO(D) Adult/Small Adult Accessories ,	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	