

NCMDR Weekly Update

16-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 16-Jul-19

Dear,
 NCMDR team is pleased to inform you that **36** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **08-Jul-19** to **14-Jul-19** In order to view more details, click the links or attachments 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **36** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **08-Jul-19** إلى **14-Jul-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Diagnostic and therapeutic radiation devices

Azurion Interventional Fluoroscopic X-ray System ,	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Azurion Interventional Fluoroscopic X-ray system.	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
LANTIS Oncology Information System Server..	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Monaco .	Elekta Inc	Medical Regulations Gate	/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Ultrasonic Diagnostic Apparatus WS80A and HS70A	Samsung Electronics	Ebrahim M. Al-Mana & Bros. Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Ultrasound Probe RIC59D and Repair RIC59ARS	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

Electro mechanical medical devices

Boston Scientific Extractor Pro RX-S Retrieval Balloon Catheter	Boston Scientific	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
MAC VU360 systems ,	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.s	
Pulsavac® Plus Wound Debridement Systems	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
# Respiratory Products Using Remote Desktop Services for Microsoft Windows Operating Systems	Vyair Medical, Inc..	Bio Standards	🔒	

In vitro diagnostic devices

RX Analyser Series ,	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.s	
Alere DDS2 Test Kits	Alere LTD	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
Elecsys Anti-CCP assay used in cobas e 411 / 601/ 602/ 801 systems	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=14536	
FTD ACE	< Diagnostics Luxembo	Integrated Gulfbiosystems	/Secure/CA/CaViewRecal	
FTD Neuro 9	< Diagnostics Luxembo	Integrated Gulfbiosystems	/Secure/CA/CaViewRecal	
FTIyo diverse	< Diagnostics Luxembo	Integrated Gulfbiosystems	/Secure/CA/CaViewRecal	
ORTHO AutoVue Innova Ultra & VISION or VISION Max	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Phadia 1000 instrument ,	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.s	

Non-active implantable devices

Basic insert for load drill guide, LOQTEQ® 4.5, round hole	aap Implantate AG.	Cure Development International Ltd	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Broach Handle	Amplitude GmbH	N/A	/Secure/CA/CaViewRecal	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Edwards CENTERA Transcatheter Heart Valve System	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14529	
GTS Trunnion Rasp	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14529	
NB797K - E.MOTION UC/PS TIB.PLAT.C'LESS μCAP T7R	Aesculap	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14529	



Ophthalmic and optical devices


Morcher Capsular Tension Rings Type 13 Right, Type 13A Right and Type 13B Right	Morcher GmbH	albasar for medical supplies	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	
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Reusable devices

TITANIUM TIP EASYTIP 2.2MM 30°	Oertli Instrumente AG	Medicals International Saudi Arabia for Maintenance & Repair	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	
UltraCheck ABP Blood Pressure Cuffs	Statcorp Medical	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	

Single-use devices

# Advincla Delineator Uterine Manipulators with Soft Koh-Efficient ,	Cooper Surgical, Inc.	Cure Development International Ltd		
# Andover Sterile CoFlex Products ,	Medline Industries Inc.....	Spectromed		
BD Connecta Plus3 White (3 way stopcock) .	BD Biosciences	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	
ElectroMist	pharmaceutical Innovations,	MEDICAL SUPPLY & SERVICE CO.	/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	
GRIPPER and PORT-A-CATH Needles	Smiths Medical International Limited	almadar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14542	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Intraluminal Staplers (ILS) ,	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.s	
# Jackson-Pratt 15 Fr and 19 Fr Round Fluted Drains .	Degania Silicone, Ltd	N/A		
Nutricare Infant Clear Nasogastric Feeding Tube 6Fr 50cm Sterile	GBUK Enteral Ltd also trading as Enteral UK	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
PERIFIX FILTER 0,2µM ISO NRFit	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
Revive Reusable Bladder Support	Rinovum Women's Health	N/A	https://ncmdr.sfda.gov.s	