

NCMDR Weekly Update

11-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 إندارات 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 إندارات السلامة.
- التواصل مع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ومع الممثل القانوني للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إشعارات إندارات 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 11-Jun-19

Dear,
 NCMDR team is pleased to inform you that **25** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **03-Jun-19** to **09-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 **25** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **03-Jun-19** إلى **09-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

#	SERVO-i Ventilators	MAQUET Inc	Gulf Medical Co.		
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Assistive products for persons with disability

Body-Weight Support Light (BWS-L)	Motek Medical B.V	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
J623 Power Wheel Chairs ("Jazy 623") fitted with Dynamic Controls Shark Power Module	Pride Mobility Products Ltd	alsandross international	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14396	

Diagnostic and therapeutic radiation devices

Philips Access CT Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Philips Incisive Computed Tomography x-ray system	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Electro mechanical medical devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Autoclavable Internal Handles with Integrated and Removable Paddles	ZOLL Medical Corp	Arabian Health Care Supply Co. (AHCSC)		
# EPI-Sense Coagulation Systems with VisiTrax	AtriCure, Inc.	Al Shoumoukh Trading for Technical and Medical Supplies		
Holter System V1.22&V1.23 Analysis Software	Edan Instruments Inc	Regulatory Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Pro-padz Liquid Gel Radiolucent Electrodes Used with ZOLL R, M, E, and X Series Defibrillators	ZOLL Medical Corp	Arabian Health Care Supply Co. (AHCSC)		

Healthcare facility products and adaptations

HyLED Surgical Light Series 7, 8 and 9	Nanjing Mindray Bio-Medical Electronics Co., Ltd.	ATTIEH MEDICO LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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In vitro diagnostic devices


Filter-Tips, 1500 µl (1024) used with QIASymphony SP/AS Instruments ,	QIAGEN Ltd	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14400	
UniCel DxH 800/600/900 Coulter Cellular Analysis System.	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	

Medical software

# Various Systems Running Windows 7 and Windows 2008	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		
# Various Systems Using Remote Desktop Services for Microsoft Windows Operating Systems	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.		

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

care&serve premium wooden tongue depressor natural	WIROS Wilfried Resbach GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Cera Vascular Plug System	Lifetech Scientific (Shenzhen) Co., Ltd.	Ameesa Medical Instruments	https://ncmdr.sfda.gov.s	
Implant Inserter S. Connection	EIT Emerging Implant Technologies GmbH	N/A	https://ncmdr.sfda.gov.s	
# SoloPath Expandable Transfemoral Systems and SoloPath Re-Collapsible Balloon Access Systems	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD		

Ophthalmic and optical devices

Brilliant Peel	Fluoron GmbH	Gulf Medical Co.	/Secure/CA/CaViewRecal	
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Single-use devices

# Advance Enforcer 35 Focal Force PTA Balloon Catheters	Cook Medical	Majal Care for Trading Est.		
Codan Extension Set	CODAN Medizinische Geraete GmbH & Co	Alwan Alnoor Trading Est.	https://ncmdr.sfda.gov.s	
LimiTorr Volume Limiting External CSF Drainage and Monitoring Systems	Integra LifeSciences	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14338	
# Microtainer Tubes with Microgard Closure	BD Biosciences	Becton Dickinson B.V.		
Sinapi Chest Drainage Range	Primed Halberstadt Medizintechnik GmbH	Al-Kawader Scientific Establishment	https://ncmdr.sfda.gov.s	
# SmartSite Syringe Administration Sets	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	