



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

07-May-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:

- 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: Yes
No


اسم المستشفى:
التاريخ:
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 07-May-19

Dear, NCMDR team is pleased to inform you that **49** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **29-Apr-19** to **05-May-19** In order to view more details, click the links or attachments 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **49** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **29-Apr-19** إلى **05-May-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
---------------	--------------	--	------	-----------------

Assistive products for persons with disability


Rapido; Squod; Forest II; Forest Kids; Express	NV Vermeiren..	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Rock 'n Play Sleepers	Fisher-Price Brands	N/A		
# Rocking Sleepers	Kids2 Inc	N/A		

Diagnostic and therapeutic radiation devices

Biograph Vision 600 and Biograph Vision 600 Edge (with VG75A or B software and the PATLAK reconstruction license)	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14232	
---	---------	---------------------------	---	--

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Philips EPIQ & Affiniti Ultrasound Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Solstice Tilting Head Fixation System	MEDTEC Inc. (CIVCO)	Medical regulations gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	
SOMATOM go.Up, SOMATOM go.Now, SOMATOM go.All, SOMATOM go.Top ,	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	

Electro mechanical medical devices

#	Alaris Pump Administration Sets	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.		
	Diego Elite Consoles	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	
	Efficia 3/5 ECG Trunk Cable, AAMI/IEC	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	
	Getinge 86-series, Collapsing pump hose	Getinge Disinfection AB	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	
	HSO SafeHeat Hand Warmer	MSP Medizintechnik GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14252	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Ingenia Ambition S (781359), Ingenia Ambition X (781356) with Magnet Energization Device (MED),	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14231	
# IntelliBridge and Patient Information Center iX Central Monitoring Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		
MEDUCORE Standard 2.	Weinmann.	Al Khateeb United Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Orchestra Base Intensive & Orchestra Base Primea.	Fresenius Kabi Ltd	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Philips HeartStart MRx with the M3539A AC Power Module	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Solero Microwave Tissue Ablation System Generator	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

Healthcare facility products and adaptations

Cracked coating fork on VOLISTA light	MAQUET Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
---------------------------------------	------------	------------------	---	--

In vitro diagnostic devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Access Total T3, Access Thyroglobulin, Access Free T4, Access GI Monitor	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14254	
ADVIA Centaur Anti-Thyroglobulin (aTG) Positive Bias, ADVIA Centaur, XP, XPT and CP	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14228	
Alere NT-proBNP Control, Alere NT-pro BNP Calibrator	Axis-Shield Diagnostics Limited	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
ARCHITECT c Systems Mixer	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
IH-QC1	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
MicroVue DPD EIA	Quidel Corporation	DULLA FOUAD HOLDING COMPA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
SD BIOLINE Chikungunya IgM	Standard Dignostics..	Tabaeb-Najd Trading Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
SureTyper Software	Linkage Biosciences Inc.	Farabi Trading Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
Sysmex SP-50 slidemaker-stainer	Sysmex Corporation	ARABIAN MEDICAL & PHARMACEUTICAL CO.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	


Non-active implantable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# 4 x 40 mm Hex Cortical Screws	TriMed Inc	N/A		
# IDEAL IMPLANT Breast Implants	Ideal Implant Inc	N/A		
MitraClip® XTR Clip Delivery System.	Abbott Vascular	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
OmniPore Surgical Implants	Matrix Surgical Pty Ltd	Al Mofadaly Trading Est.	https://ncmdr.sfda.gov.sa	
# SoloPath Expandable Transfemoral Systems and SoloPath Re-Collapsible Balloon Access Systems	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD		
# Wingspan Stent Systems	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY		
Xenform Soft Tissue Repair Matrixes, Uphold Lite with Capio SLIM Vaginal Support System, Polyform Synthetic Mesh, and Pinnacle™ LITE Pelvic Floor Repair	Boston Scientific	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14239	

Ophthalmic and optical devices


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Ceiling unit CU 3-5x in combination with the operating microscope HS Hi-R NEO 900 / A / A NIR	Möller Medical GmbH	Techno-Orbits Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14234	

PL770SU - CAIMAN MARYLAND NON ARTICULAT.D5/36 OMM	Aesculap	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14238	
---	----------	------------------	---	--


# Select Zeiss IOLMaster Optical Biometry Systems	Carl Zeiss Meditec Inc	Gulf Medical Co.		
---	------------------------	------------------	---	--

Single-use devices

Arrow PICC and JACC kit	Arrow International Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14238	
-------------------------	-------------------------	------------------	---	--

# B Braun 2 gm Ceftazidime and Dextrose in 24 x 50 mL DUPLEX Bags	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv		
---	---------------------	---	---	--

BD PhaSeal™ C61 Secondary Set	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14238	
-------------------------------	-----------------------------	-----------------------	---	--

# MAHURKAR and Argyle Acute Hemodialysis Catheters	Medtronic SA	Medtronic Saudi Arabia		
--	--------------	------------------------	---	--

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Monoject Standard Hypodermic Needles ,	Covidien LLC....	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
# Monoject Standard Hypodermic Needles ,	Covidien LLC....	Medtronic Saudi Arabia		
Occlutech Delivery Set	Occlutech Holding AG	Medglories Medical Co. Ltd.	https://ncmdr.sfda.gov.s	
Safety pin no. 3, 1 piece per pouch	Sterisets Medical Products.	N/A	https://ncmdr.sfda.gov.s	
Two-Lumen Central Venous Catheterization Kit/ - Set with Blue Flex Tip Catheter	Arrow International Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14237	
Yankauer Suction Tubing, Foley Catheter, Thoracic Catheter and Oxygen Tubing	Cardinal-Health	MEDICARE DRUG STORE COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14221	
Zenith Alpha Thoracic Endovascular Graft..	Cook Medical Europe Limited	Majal Care for Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	