

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: 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.
- 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 المظلمة 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


02-Apr-19

Dear,
NCMDR team is pleased to inform you that **33** new FSCA/recalls for medical devices and products posted on SFDA website for the period of 25-Mar-19 to 31-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 **33** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 25-Mar-19 إلى 31-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

#	Various MEDUMAT, MODUL, and ULM Devices	Weinmann.	Al Khateeb United Trading Est.		
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Dental devices

PalTop	Keystone Dental Inc.	N/A	/Secure/CA/CAViewRecal	
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Diagnostic and therapeutic radiation devices

MobileDiagnost wDR	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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Electro mechanical medical devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# 6 Fr Sherpa Active Catheters	Medtronic SA	Medtronic Saudi Arabia		
CATSmart Vacuum Pump	Fresenius Kabi Ltd	Gulf Medical Co.	https://ncmdr.sfda.gov.s	
# Diego Elite Consoles	Olympus	Salehiya Trading Est.		
# EV1000 Clinical Platforms	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCC)		
# Extraneal Peritoneal Dialysis Solution	Baxter Healthcare	Baxter AG		
GETINGE Cabinet Return Sluice 6613-R	Getinge Disinfection AB	Gulf Medical Co.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
# GlideScope Video Laryngoscopes	Verathon Inc	Techno-Orbits Establishment		
LW Scientific ZIP IQ PCV Centrifuge	LW Scientific, Inc.	N/A	https://ncmdr.sfda.gov.s	
# Performance Series Sagittal Blades	Stryker Instruments	Al-Faisaliah Medical System		
# Select Myoelectric Hands	HUGH STEEPER LTD	husn al Emirat Est.		

Healthcare facility products and adaptations

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# FLUSHMATE II 501-B Pressure-Assisted Toilet Operating Systems	Flushmate	N/A		

Hospital hardware

# Berchtold CHROMOPHARE F 528 and F 628 Surgical Light System Light Head Covers	Stryker Communications	Al-Faisaliah Medical System		
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In vitro diagnostic devices



Accelerate Pheno system	Accelerate Diagnostics Inc	Creative Healthcare Establishment	https://ncmdr.sfda.gov.s	
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cobas p 501 / 701 post-analytical units ,	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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Randox Blood Gas Control Level 2	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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# Sekisui Diagnostics OSOM Ultra Flu A & B Tests	Medline Industries, Inc.	Cure Development International Ltd		
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Medical software

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
BD Synapsys Microbiology Informatics Solution	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
# Various Devices Using Conexus Telemetry Protocol	Medtronic SA	Medtronic Saudi Arabia		
# Vision+/Outcomes Manager CHA2DS2-VASc Calculators	Vision	N/A		

Non-active implantable devices


Avitus-Bone Harvester w/ Filter Insert - 5mm	Avitus Orthopaedics, Inc.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
Drill Mini-Trephination 2.0mm	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
JOURNEY II XR TIBIAL POSTERIOR KEEL PUNCH	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
Polished Finned 1 Piece Tibial Tray 71mm	Biomet Spain Orthopaedics SL	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
# Sterile Distraction Screws	Tedan Surgical Innovations Llс	Medical Regulations Gate		


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
TRIAL Titanium Shell left with strap 60 mm	Peter Brehm	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Ophthalmic and optical devices

BVI Visitec Soft Tip Cannula	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Single-use devices

# Anchor Tissue Retrieval Systems	ConMed Corporation.	ProMedEx		
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# ChemoPlus Spill Kits and Protective Wraparound Goggles	Cardinal-Health	MEDICARE DRUG STORE COMPANY		
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Miller and Fogarty Atriostomy Catheters	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
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Nelaton Urinary Catheter, Feeding Tube Metric, FilterFlow Suction Handle CH24, Forceps Blue	ConvaTec	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14058	
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