

NCMDR Weekly Update
16-Apr-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.

عزيمي،
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.

• الإشعارات المظللة بالأصفر تشير الى سحب او إتلاف جهاز طبي.

• 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

• الممثلين القانونيين/الموزعين في هذا التقرير قد يختلفون عن الممثلين القانونيين/الموزعين الذين تتعاملون معهم.

• The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI.


• هذه العلامة (#) في الجهة اليسرى من التقرير تشير إلى ان اشعار انذار السلامة من منظمة (ECRI).

• Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

• لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.

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Dear, NCMDR team is pleased to inform you that **39** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **08-Apr-19** to **14-Apr-19** In order to view more details, click the links or attachments 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **39** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **08-Apr-19** الى **14-Apr-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

Oxylog VE300	aeager Medical Systems	Draeger Arabia Co. Ltd.	/Secure/CA/CaViewRecal	
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Dental devices

ANKYLOS Tri-Spade Drill GS A8	DENTSPLY International	Branch of DENTSPLY International Inc	https://ncmdr.sfda.gov.s	
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# Medline Sparkle Fresh Fluoride Toothpaste Contained in Moore Medical Kits	Medline Industries, Inc.	Cure Development International Ltd		
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Sebond Implant	Schutz Dental Group	N/A	/Secure/CA/CaViewRecal	
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Diagnostic and therapeutic radiation devices

	MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
#	Aquilion ONE Vision and Aquilion PRIME CT Scanners	Canon Inc	Gulf Medical Co.		
	Artis zee and Artis Q/Q.zen systems	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.s	
#	DRX-Ascend Systems and Q-Rad Systems	Carestream Health	Samir Trading and Marketing CJSC.		
	EKOS Control System 4.0 - Connector interface cabl	EKOS Corp	Arabian Trade House Est.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
	EMR Manager (PACS)	Vepron AG	N/A	https://ncmdr.sfda.gov.s	
#	Rüsch Lasertubes	Teleflex Medical	Medical Technology Trading Compa		

Electro mechanical medical devices

	Auriga 30 Laser System	Boston Scientific	Gulf Medical Co.	https://ncmdr.sfda.gov.s	
	Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=14141	
	CSZ Haemotherm 400CE System	Cincinnati Sub-Zero Products Inc	Al Shoumoukh Trading for Technical and Medical Supplies	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Defigard Touch 7.	Schiller AG	cal supplies & Services Co.Ltd Med	/Secure/CA/CaViewRecal	
Duodenovideoscope TJF-160VR ,	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.s	
Nokia BPM+ - Wireless Blood Pressure Monitor	Withings Sas	N/A	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	
SORIN Heater-Cooler System 3T	LivaNova PLC	cigalah group	https://ncmdr.sfda.gov.s	
# T7 Cannulated and Solid Drivers	Zimmer, INC....	Medical Regulations Gate		
Ultrafilter U9000 ,	Baxter Corp Canada	Baxter AG	https://ncmdr.sfda.gov.s	
Wolf 445nm	Arc Laser GmbH	N/A	Secure/CA/CaViewRecall	

In vitro diagnostic devices

Alinity i System ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
PALUTOP +4 OPTIMA	Biosynex S.A.	WAREED ALHAYAT	https://ncmdr.sfda.gov.s	
Procleix HEV Assay	Grifols-Spain	DULLA FOUAD HOLDING COMPA	/Secure/CA/CaViewRecal	
Vitamin D total II, Elecsys Vitamin D total II	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
VITEK 2: AST-N254 , AST-N330, AST-N371 test kits	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
VITROS 250 and 350 Chemistry Systems ,	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	

Non-active implantable devices

aixstent Duodenum TTS	bess pro gmbh	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
Biomet RingLoc Hip System SelfTapping Bone Screw	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=2&rid=14	
Integra bioBLOCK Resorbable subtaler Implant	Integra Limited	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
iTotal CR Total Knee Replacement System,	ConforMIS	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=2&rid=14	
# Physica ZUK All-Poly Tibial Plates	Limacorporate S.p.a.	N/A		
TACTYS - IPP Prosthesis - Proximal Surface	Stryker Instruments	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	

Ophthalmic and optical devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Dornier Standard Diode and Nd:YAG Lightguides	Dornier MedTech GmbH	ATTIEH MEDICO LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	

Single-use devices

BD MaxZero™ Needleless Connector and associated extension sets	Becton, Dickinson And Company	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14133	
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Component Neuro swab in Molnlycke Procedure trays	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
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Cruiser	BIOTRONIK UK Ltd	WATEEN MEDICAL CO	/Secure/CA/CaViewRecal	
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Microbore Y-Type Extension Set and Catheter Extension Set with Clearlink	Baxter Healthcare.	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14157	
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VariFit Sterile Single Use Adult Thigh Cuffs, Single Port, Single Bladder	Delfi Medical Innovations Inc	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14128	
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Visiwipe Instrument Wipe 73 x 73mm	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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