

NCMDR Weekly Update
29-Jan-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.
- 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 29-Jan-19

Dear, NCMDR team is pleased to inform you that **23** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **21-Jan-19** to **27-Jan-19** In order to view more details, click the links or attachments 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **23** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **21-Jan-19** إلى **27-Jan-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Active Implantable Devices

29901 CareLink Encore™ Programmer Power Supply Model 26907 ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=13771	
Adapta Dual Chamber Pacemakers ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13767	
Programmer Software Update Supporting the Micra Transcatheter Pacing System ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13767	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Programmer Software Update Supporting the Micra Transcatheter Pacing System ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13775	

Anaesthetic and respiratory devices

# Medline-Labeled Sterile Water Manufactured by Smiths Medical	Medline Industries, Inc.	Cure Development International Ltd		
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Diagnostic and therapeutic radiation devices

Senographe Crystal Nova	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13775	
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Electro mechanical medical devices

Captus 3000 Thyroid Uptake System	Capintec Inc.	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13775	
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Electronic Thermometer supplied in Tiny Tots First	Shaoxing Fuqing Medical Products Co Ltd	first focuz Limited Company	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=13775	
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# Insulin Infusion System Bolus Dose Calculators	Cellnovo Ltd	N/A		
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Percuvance(R) Percutaneous Shaft 36cm and 29cm	Teleflex Medical. Teleflex Medical..	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=13775	
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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In vitro diagnostic devices

Dimension Vista® LOCI® Reaction Vessels	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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# DxA 5000 Automation Systems	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd		
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ELITech V-Twin Analyzer	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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PREMIER Cryptococcal Antigen enzyme immunoassay (EIA)	Meridian Bioscience Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13769	
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T-Cell Select	Oxford Immunotec Ltd	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
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VITEK 2 - Card Pouch Integrity	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Non-active implantable devices

Artikon.genu-bi-lock System-KneeJoint Set with locking mechanism	Streifeneder ortho.production GmbH	Farabi Trading Establishment	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=13778	
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Lambotte chisel, 20mn	aap Implantate AG.	Cure Development International Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Ophthalmic and optical devices


MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
DRI OCT Triton/DRI OCT Triton plus	Topcon Medical Laser Systems	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Single-use devices

DeRoyal(R) Enteral Safe Feed Tube, REF 542465	DeRoyal Industries, Inc..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Edwards Lifesciences IntraClude Intra-aortic Occlusion Device	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=13788	
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Obstetric Forceps	er Medical GmbH & Co	N/A	/Secure/CA/CaViewRecal	
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# Sage Products Independent Care Systems	Sage Products LLC	Teriag International		
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