



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

14-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 إلى سحب أو 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 14-May-19

Dear, NCMDR team is pleased to inform you that **34** new FSQA/recalls for medical devices and products posted on SFDA website for the period of 06-May-19 to 12-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 **34** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 06-May-19 الى 12-May-19 ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

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

#	Various Pacemakers	Medtronic SA	Medtronic Saudi Arabia		
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Anaesthetic and respiratory devices

#	eSeries Ventilators	o Medical Technologie	Dar Al Najat Medical Tech.		
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	Heat exchanger and adult infusion set with filter and needle-free injection site- TEIDE 150	CAIR LGL	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14269	
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	Matrx Digital MDM Mixer	Air Liquide Medical Systems	N/A	https://ncmdr.sfda.gov.s	
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Dental devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Maestro .018 UL1 Orthodontic Bracket	Ortho Organizers Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	


Diagnostic and therapeutic radiation devices


#	O-Arm 1000 Imaging Systems	Medtronic SA	Medtronic Saudi Arabia		
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Electro mechanical medical devices

#	Alaris Pump Administration Sets	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	Please check the Email for attachment file	
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	Auriga 30 Laser System	Boston Scientific	Gulf Medical Co.	https://ncmdr.sfda.gov.sa	
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#	Connected OR Carts	Stryker Endoscopy	Al-Faisaliah Medical System		
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#	enFlow IV Fluid and Blood Warmers	Vyair Medical	Spectromed		
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	Prismaflex devices with software version 8.10	Baxter Healthcare	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
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	Wolf 445nm	A.R.C. Laser GmbH	Arabian Salmiya Trading Est.	Secure/CA/CaViewRecall	
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Healthcare facility products and adaptations

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Tasy Electronic Medical Record Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		

In vitro diagnostic devices

Access Free T3, Access Total T3, Access Free T4, Access GI Monitor (GI Mon), Access Thyroglobulin (Tg), Access Thyroglobulin Antibody II (TgAbII)	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14280	
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# ACDA Anticoagulant Solution	Macopharma SAS	Dar ALKarmel		
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G-6-PDH Deficient and Normal Controls	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14259	
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IMMAGE Immunochemistry Systems Immunoglobulin M (IGM) Reagent .	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14278	
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Medica Wash1- Wash solution used prior to Lipase assay on the EasyRA clinical chemistry analyzer REF 10680	Medica Corporation.	AL OSOOL MEDICAL TRADING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14278	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
VITROS 3600, 5600, and XT 7600 Systems ,	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	


Non-active implantable devices

Edwards PASCAL Transcatheter Valve Repair System	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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# Endball Systeme de Ballon Intra-gastrique	Endalis	N/A		
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NI-C311 Energy Hybrid Knie	Nabtesco	N/A	https://ncmdr.sfda.gov.s	
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# Reshape Medical Intra-gastric Balloon	Reshape Medical Inc	Dar Al-Zahrawi Medical Co. LLC		
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# Spatz3 Adjustable Balloon System Insertion Kits.	SPATZ FGIA, INC..	MEDICAL INNOVATIONS EST.		
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twinSys impactor with offset	Mathys.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.s	
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Reusable devices

2.7 Degree Angled Sagittal Saw attachment and 2.7 Degree Straight Sagittal Saw attachment	MAKO Surgical Corp	Zimmo Trading Establishment.	https://ncmdr.sfda.gov.s	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Single-use devices

4 Fr EverlinQ EndoAVF System	TVA Medical, Inc.	C.R. BARD Saudi Arabia	https://ncmdr.sfda.gov.s	
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BVI Ophthalmic Instrument Wipes, Wicks and Corneal Light Shield Sponge Products	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14270	
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EZ Derm Porcine Xenografts	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	https://ncmdr.sfda.gov.s	
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IntroFlex Introducers ,	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCC)	https://ncmdr.sfda.gov.s	
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# MaxPlus Clear Needleless Connectors	Becton, Dickinson And Company	Medical Regulations Gate		
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Prismaflex and MARS Treatment Sets	Baxter Healthcare	Baxter AG	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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# TIVA Infusion Sets ,	Europlaz Technologies	N/A		
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Tristel Trio Wipes System, Tristel Rinse Wipe	Tristel Solutions Ltd	Bio Standards	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
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