

NCMDR Weekly Update

19-Mar-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 **28** new FSCA/recalls for medical devices and products posted on [SFDA website](#) for the period of **11-Mar-19** to **17-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 **28** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **11-Mar-19** إلى **17-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


ACCULAN 4 OSCILLATING SAW STRAIGHT	Aesculap	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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Diagnostic and therapeutic radiation devices

# MR-Conditional Halo System Devices	Ossur	Al Ewan Medical Company		
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UROSKOP OMNIA and UROSKOP OMNIA MAX	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
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Electro mechanical medical devices

# 3T Heater-Cooler Systems.	LivaNova PLC	cigalah group		
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Cordis Vista Brite Tip® & ADROIT Guiding Catheters	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	

Giraffe Bedded Warmer/Panda iRes Warmer	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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In vitro diagnostic devices

Alinity ci-series System	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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Alinity I, c and s Processing Module	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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Alinity s System	Abbott	cal supplies & Services Co.Ltd Med	/Secure/CA/CAViewRecal	
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Atellica® IM 1300 Analyzer, Atellica® IM 1600 Analyzer & Atellica® Sample Handler Prime	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=14000	
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Cepheid Respiratory Control Panel	Microbiologics	Q.M.S. Co. Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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ChromID CPS/Horse Blood Agar.	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec	
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# FilmArray Blood Culture Identification Panels.	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
FilmArray Gastrointestinal (GI) Panel.	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=14	
FTD 10.2 Fever and rash	Fast Track Diagnostics Luxembourg S.à.r.l.	Integrated Gulfbiosystems	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
Liquid Cardiac Control	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
NK044.OPT - Optilite C-Reactive Protein Reagent	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
Reagent CRP FS	s Diagnostic Systems G	ALGhuyum Scientific Trading	/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	

Medical software

# Various Systems Using Microsoft Windows Operating Systems	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.		
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Non-active implantable devices

ALLUX prosthetic knee joint - internal software	Nabtesco	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
Genex Putty 5cc	Biocomposites Ltd	Amal Fahed Ali Algufidi	Secure/CA/CAViewRecall.aspx?caid=6&rid=13	
HeartMate 3 Coring Tool	Thoratec Corp	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=13	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Reaxon Direct, Reaxon Nerve Guide	Medovent GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=14	

Single-use devices

Durex Pleasure Pack.	Reckitt Benckiser Healthcare	Cigalah Group	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=14	
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INTRAPUR NEONAT I.V.FILTER 0.2MICRON	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=14	
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# Mylan EpiPen and EpiPen Jr Auto-Injectors	Medline Industries, Inc.	Cure Development International Ltd		
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Pneumosure Heated Tubeset with RTP, High Flow Tubeset with RTP, and High Flow II Tubeset	Stryker Communications	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=14006	
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# Vacutainer Eclipse Blood Collection Needles	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.		
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