



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

11-Dec-18

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 المظللة 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 11-Dec-18


Dear, NCMDR team is pleased to inform you that **30** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **03-Dec-18** to **09-Dec-18** In order to view more details, [click the links or attachments](#) 

عزيزي،
يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **30** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **03-Dec-18** الى **09-Dec-18** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

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

Cardiac Resynchronization Therapy (CRT) pacemakers (CRT-Ps) and defibrillators (CRT-Ds) ,	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13564	
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# Model 1000 SenTiva VNS Therapy Generators	LivaNova PLC	cigalah group		
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Sonata ti100 ,	Elektro-Medizinische Geräte	ATTIEH MEDICO LTD	Secure/CA/CaViewRecall	
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Diagnostic and therapeutic radiation devices


I-View Contrast Enhanced Digital Mammography,	Hologic Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Various Endoscopes ,	Olympus	Salehiya Trading Est.		

Electro mechanical medical devices

# da Vinci Xi Surgical System Arm Sensor ,	Intuitive Surgical Inc	Gulf Medical Co.		
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# da Vinci Xi Surgical System Arm Sensor ,	Intuitive Surgical Inc	Gulf Medical Co.		
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# EDS Light Suspension Central Axis Component of Visum LED Surgical Lighting Systems ,	Stryker Communications	Al-Faisaliah Medical System		
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# Fibro-Cleaner Automatic Endoscope Reprocessors	Getinge Disinfection AB	Gulf Medical Co.		
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Medtronic HeartWare HVAD System Battery Charger ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
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PNEUMOCLEAR	of Medicine GmbH (her	Medtronic Saudi Arabia	/Secure/CA/CaViewRecal	
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# ProtectIV Plus Safety Intravenous Catheters	Smiths Medical International Limited	almadar medical Est.		
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
RotoProne Therapy System	Arjo Hospital Equipment AB.	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

# TC-115 Balloon Catheters	VascoMed GmbH	WATEEN MEDICAL CO		
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Healthcare facility products and adaptations

Invacare 9805 and 9805P Hydraulic Patient Lifts	Invacare Corporation...	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
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In vitro diagnostic devices

AIA900 Automated Immunoassay Analyzer	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	
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cobas c 311/501/502/701/702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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COBAS INTEGRA® 400 plus and cobas c 111 analyzer	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13	
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IMTEC-β2-Glycoprotein I-Antibodies IgG	HUMAN Gesellschaft für Biochemica und Diagnostica GmbH	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Lactose intolerance quick test	BIOHIT OYJ	Qualb Al-Hayat Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
QSight 210 MD Mass Spectrometer Simplicity 3Q MD	PerkinElmer Life and Analytical Sciences	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13	

Laboratory equipment

BD BBL Trypticase Soy Agar with 5 Sheep Blood, Catalog No. 221261	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=13567	
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Non-active implantable devices

CERAMENT G, CERAMENT BONE VOID FILLER and CERAMENT V	Bonesupport	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13	
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# LFIT V40 Femoral Heads ..	Howmedica Osteonics Corp.	Zimmo Trading Establishment.		
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Ophthalmic and optical devices

# SmartScope Fibers	ForTec Medical	N/A		
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Reusable devices

CWP 800 RO1 220-240V/ 380- 415V 50Hz, CWP 800 HW 220- 240V/ 380-415V 50Hz, Clinic Panel	Gambro Lundia AB	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=13573	
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Single-use devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Balloon Guide Catheters 9F ,	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.s	
First Aid Sterile Gauze Pad	ASO, LLC	N/A	https://ncmdr.sfda.gov.s	
MultiTrack Angiographic Catheter (MMTA)	NuMED, Inc.	Ameesa Medical Instruments	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
# Nano Corkscrew Suture Anchors ,	Arthrex, Inc	Medical Regulations Gate	