

NCMDR Weekly Update

18-Jun-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:

*** Kindly respond to the NCMDR weekly report in both cases either you are affected or not affected.**

*** نأمل الرد على تقرير المركز الوطني لبلاغات الاجهزة و المنتجات الطبية في حالتي التأثر أو عدم التأثر.**

- 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:

اسم المستشفى:

Date:

التاريخ:

Hospital affected by any medical device/product in this report: Yes

No


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 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 18-Jun-19

Dear, NCMDR team is pleased to inform you that **32** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **10-Jun-19** to **16-Jun-19** In order to view more details, click the links or attachments 

عزيمي،
 يود فريق عمل المركز الوطني لبلغات الأجهزة والمنتجات الطبية إعلامكم بنشر **32** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **10-Jun-19** إلى **16-Jun-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


Intensive Care Ventilators elisa 300, elisa 500, elisa 600, elisa 800 und elisa 800VIT	Lowenstein Medical GmbH &Co.KG	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14408	
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Dental devices




Healing Abutment CC RP Ø3.6x5mm	Nobel Biocare Services AB	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14408	
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Diagnostic and therapeutic radiation devices

Artis Zee and Artis Q systems	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14408	
BrightView SPECT, BrightView X and BrightView XCT	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14408	
CyberKnife M6 and CyberKnife VSI Secondary Collimation Subsystem	Accuray Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14403	


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# FCR Capsula X and Carbon X Computed Radiography Cassette Readers	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY		
InterStim Therapy Programmer Compatibility	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Revolution CT scan ,	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.s	

Electro mechanical medical devices


Advanced Perfusion System 1 ,	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
BIOSAFE MD-smart	Cryotherm GmbH & Co	N/A	https://ncmdr.sfda.gov.s	
# C-10 Probetesters	ES Medical AB	N/A		
OMNIBotics iBlock Cutting Guide ,	OMNIlife science	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# Prometra II Programmable Pump .	Flowonix Medical	N/A		
Simple Locking Intramedullary (SLIM) System (SLM-HND100)	Pega Medical...	Tina Medix Technologies Int. Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Therapy chair ZeroG with models TCZ-LUX and TCZ-EX	Novak M d.o.o.	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
# Ultra-Drive Hose/Drape Assemblies and Ultra-Drive Irrigation Tubing Assemblies	Zimmer, INC...	Medical Regulations Gate		

In vitro diagnostic devices

Alinity ci-series System Control Module ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
MRSASelect II	Bio-Rad Laboratories Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ORTHO BioVue® System Cassettes ,	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Tri-Level Cardiac Control	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.s	
# VIP Radioimmunoassay Kits	DIAsource Immunoassays..	ABDULLA FOUAD HOLDING COMPANY		


Non-active implantable devices

Biomet Oxford Partial Knee Phase 3 / Domed Lateral Femoral Drill Guide .	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14421	
Lineum 4.35mm x 28mm Translation Screw ,	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
# UNI-Graft K DV Vascular Prostheses	Aesculap...	ProMedEx		

Reusable devices

DA8K-10-14453 British standard power cord .	Shenzhen Mindray Biomedical Electronics Co., Ltd..	International Medical Supplies Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
DA8K-10-14453 British standard power cord ,	Shenzhen Mindray	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Sterile Nail Nipper ,	Centurion Medical Products	Bio Standards	https://ncmdr.sfda.gov.s	

Single-use devices

# AXIUS Blower Mister	Getinge Disinfection AB	Gulf Medical Co.		
JELCO Hypodermic Needle-Pro EDGE ,	Smiths Medical International Limited	almadar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
NxStage PureFlow B Solution ,	NxStage Medical, Inc.	REDWAN MEDICAL SERVICES	https://ncmdr.sfda.gov.s	
Pleur Evac	Teleflex Medical.	Arabian Trade House Est.	/Secure/CA/CaViewRecal	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
The Disposable Fleece Drape F/GA419/GD417/GD421	Aesculap	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	