

NCMDR Weekly Update

08-Sep-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 08-Sep-19

Dear,
 NCMDR team is pleased to inform you that **49** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **01-Sep-19** to **05-Sep-19** In order to view more details, click the links or attachments 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **49** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **01-Sep-19** إلى **05-Sep-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

ABL90 FLEX..	Radiometer America Inc	Salehiya Trading Est.	/Secure/CA/CaViewRecal	
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Assistive products for persons with disability

Achilles EXP11 Systems with power cords.	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Concerto & Basic Shower Trolley.	Arjo Huntleigh	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa	
Cooltechnology Device	HIGH TECHNOLOGY PRODUCTS, SL	ALRIYADH INT'L CO FOR MEDICAL EQUIPMENTS	https://ncmdr.sfda.gov.sa	
Giraffe OmniBed Carestation	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa	

Dental devices




NuOss Cancellous 1 gram /2.4cc Particle Size .25-1.0mm ,	Ace Surgical Supply Co., Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
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Diagnostic and therapeutic radiation devices

Monaco RTP System....	Elekta Inc	Medical Regulations Gate	https://ncmdr.sfda.gov.sa	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
S7-3t & S8-3t Transesophageal (TEE) Transducers ,	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

Electro mechanical medical devices


ApexPro Telemetry server ,	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Automated Ankle-Brachial Index measuring device	MESI, development of medical devices, ltd	Raz medical	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Depth Electrodes	ech Medical Instrument	Al-Nozha Medical Est	/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
# G5 Mobile Receivers	DexCom Inc	Bio Standards		
Heater Unit HU 35, 230 V ,	MAQUET Cardiopulmonary	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Heater Unit HU 35, 230 V ,	MAQUET Cardiopulmonary	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
# Irrimax Debridement and Cleansing Systems	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.		
LogiCal Pressure Monitoring Option Kit, Clear, 150cm	Smiths Medical International Limited	almadar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
# T34 Ambulatory Syringe Pumps	Caesarea Medical Electronics Ltd	N/A		

In vitro diagnostic devices

ARIES System, ARIES M1 System	Luminex Molecular Diagnostics Inc	Hatem I. Alshedwy Comm. Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Atellica® IM 1300 Analyzer & Atellica® IM 1600 Analyzer. ,	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
BD FACSLytic Flow Cytometer .	BD Biosciences	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Dimension® Sample Probe Cleaner	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
K6460 Triple Quadrupole MS	Agilent Technologies..	Cigalah Group	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Medizym T.R.A. human	Medipan GMBH	Raez Environmental System & Advanced Technologies	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ORTHO BioVue System ABD Confirmation Cassette	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
Rheumatoid Factor Standard and Liquid Protein Calibrator ,	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14726	
ROTEM ex-tem	TEM Innovations GmbH	Alyam Technical Est.	/Secure/CA/CaViewRecal	
SYNCHRON Systems Benzodiazepine (BNZG) Reagent ,	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14711	
ThermoScientific Oxoid Meropenem 32 M.I.C.E. strip, MA0121D&F	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14716	
Tina-quant Soluble Transferrin Receptor , STFR	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
VaccZyme Human Anti-Haemophilus Influenzae type b	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
VIDAS FT4.	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	/Secure/CA/CaViewRecal	

Non-active implantable devices

Calcar Trimmer Shaft	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Metafix stem size 4 ,	Corin Group plc	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
Modulus, Modulus-R and Revision modular femoral stems .	Limacorporate	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14711	
# Powerflex PRO PTA balloon dilation ,	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB		
REX Cement Stop	ierings Orthopaedics B.	Medical Regulations Gate	/Secure/CA/CaViewRecal	
Sidus Stem-Free Shoulder Humeral Head	Zimmer, INC....	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Triathlon Femoral Distal Augment	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	https://ncmdr.sfda.gov.s	
Single-use devices				
Ad-Tech Product Catalogue	Ad-Tech Medical Instrument Corp	Al-Nozha Medical Est	https://ncmdr.sfda.gov.s	
# CanGaroo Envelopes	Aziyo Biologics, Inc	Medical Technology Trading Company		
CM Jamshidi Crown Bone Marrow biopsy/Aspiration Needle with MAC	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&rid=14731	
DOSIFUSER	Leventon S. A. U.	Sarabeel Commercial Est.	/Secure/CA/CaViewRecal	
Medline Sterile Piston Irrigation Syringe Tray with Saline	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
# Microtainer K2E Tubes	BD Biosciences	Becton Dickinson B.V.		
Primary Warmer Packs Containing Vyair enFlow Disposable Cartridges .	Medline Industries, Inc.	Cure Development International Ltd	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&rid=14710	
Sterile Absorbent cotton O.R towels	Medline Industries, Inc.	Cure Development International Ltd	https://ncmdr.sfda.gov.s	
UROMED catheterisation kits, CYSTOBAG and FLUXOBAG	UROMED Kurt Drews KG	AL-MUHAIZEE TRADING SERVICES COMPANY	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Various Haemodynamic Monitoring Kits ,	ICU Medical, Inc	AL-KAMAL Import	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec	
Weinmann Adult MEDUCORE Multifunctional Electrodes	Weinmann.	Al Khateeb United Trading Est.	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	