



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

09-Apr-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: 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 09-Apr-19

Dear,
 NCMDR team is pleased to inform you that **58** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **01-Apr-19** to **07-Apr-19** In order to view more details, [click the links or attachments](#) 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **58** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **01-Apr-19** الى **07-Apr-19** ، 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

WiSE CRT Transmitter	EBR Systems, INC	N/A	https://ncmdr.sfda.gov.s	
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Anaesthetic and respiratory devices

BMV Filterkassette highflow/TRACHE OCUR HME Cassette Highflow	BMV Bender Medical Vertrieb GmbH	N/A	https://ncmdr.sfda.gov.s/Secure/CA/CAViewRecall.aspx?caid=6&rid=14121	
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VentStar Helix heated breathing circuits and Set2go	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.s/Secure/CA/CAViewRecall.aspx?caid=6&rid=14	
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Assistive products for persons with disability

Alu CARLO Classic	BEKA Hospitec GmbH	N/A	/Secure/CA/CAViewRecal	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Shark Power Module exchange	Invacare Corporation...	Bio Standards	https://ncmdr.sfda.gov.s	
Wheelchair CLEO Ti	Hoggi GmbH	N/A	https://ncmdr.sfda.gov.s	

Dental devices



Single-patient use drills for NobelReplace (Tapered Drills, Dense Bone Drills, Screw Taps), Guided Start Drills/Counterbores and Guided Counterbores for NobelReplace, Implant Retrieval Instruments and Abutment Screw Retrieval Instruments	Nobel Biocare Services AB	Medical Regulations Gate	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&rid=14089	
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Diagnostic and therapeutic radiation devices

AIR Anterior Array	GE Healthcare	GE Healthcare	/Secure/CA/CaViewRecal	
Brainlab RT Elements Radiation Treatment Planning Software	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&rid=14096	
Cios Alpha VA20, VA30	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.s	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Detector Mounting Screws for Nuclear Medicine Systems	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
MRIdian Linac System	Viewray Incorporated	N/A	https://ncmdr.sfda.gov.sa	
Prestige II, Prestige VH, Prestige SI, Prestilix 1600X, Precision 500D, Flexmed, PROTEUS XR/A and SILHOUETTE VR	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14114	

Electro mechanical medical devices

#	ADAP-2000 and ADAP-2000-12 Disposable Adapters	Remington Medical	N/A		
	Cardiohelp Emergency Drive	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa	
#	Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology	Medtronic SA	Medtronic Saudi Arabia		
	Granumix plus, DIAMIX	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ncmdr.sfda.gov.sa	
	GRP Handles.	oskopische Gerate Gm	Alnawras Global Healthcare	/Secure/CA/CaViewRecall.aspx	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
HeartMate 3™ Outflow Graft & HeartMate 3™ Left Ventricular Assist System (LVAS) kit .	Thoratec Corp	Arabian Trade House Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14094	
ICU Medical, Transpac IV Monitoring Kit With Safeset Reservoir and Blood Sampling Port	ICU Medical, Inc	AL-KAMAL Import	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14077	
IntelliVue MX40 Monitors	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14085	
Lithium-ion Rechargeable Batteries for the Philips MX40 Wearable Monitor	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14085	
# Model 5008 and Model 5008S Hemodialysis Machines	Fresenius Medical Care.	Fresenius Medical Care GmbH		
Molnlycke Detachable EndoRetrieval Pouch	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14094	
PADSY-Holter with the Holter- ECG Systems Sirius and Antares with LiveECG Recorder	Medset Medizintechnik GmbH	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14102	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
The Infinity® Acute Care System™ (IACS) & Standalone Infinity® M540 patient monitor .	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	

TM55 Stress Testing Treadmills ,	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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Hospital hardware

MEERA mobile OR-Table	MAQUET Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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In vitro diagnostic devices

Alinity hq Analyzer .	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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ARIES products	lex Molecular Diagnosti	Hatem I. Alshedwy Comm. Est.	/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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BILD2 (Bilirubin direct Gen.2) and cobas c 701 / 702	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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BÜHLMANN IBDoc	BUHLMANN LABORATORIES AG	MEDICAL INNOVATIONS EST.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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Dimension® Integrated Chemistry Systems ,	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14088	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
G-6-PDH Deficient and Normal Controls	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
IH-Com Kit Fullversion, IH-Com Kit For Reader	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
Lyphochek Specialty Immunoassay Control	Bio Rad.	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
ORGENTEC ENAcombi ELISA, ORG 514	ORGENTEC Diagnostika GmbH	REDWAN MEDICAL SERVICES	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
S. AIA-PACK ACTH	Tosoh Corporation	DULLA FOUAD HOLDING COMPA	/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	
ThermoScientific Oxoid Brilliance Staph 24 Agar	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14	

Laboratory equipment

#	Veritor Plus Analyzers and Veritor System Readers	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.		
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Non-active implantable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# 6 mm GORE PROPATEN Vascular Grafts and 6 mm GORE-TEX Stretch Vascular Grafts	W.L. Gore & Associates Inc.	Med Surg Supplies		
Femoral Neck System Insert for Insertion Handle	Synthes GmbH.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Foot and Ankle Inst. (Drill / Tap and Countersink)	Zimmer Biomet. Zimmer Biomet	Zimmer Biomet Asel Alarabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
Geistlich Bio-Oss Pen	Geistlich Pharma AG	Thimar Al Jazirah Healthcare Co.	https://ncmdr.sfda.gov.s	
iTotal Posterior Stabilized (PS) Knee Replacement System.	ConforMIS	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14075	
OnX Aortic Heart Valve	CryoLife, Inc.	Almarfa Medical	https://ncmdr.sfda.gov.s	
Rebound HRD / HRD-V	ARB Medical LLC	N/A	https://ncmdr.sfda.gov.s	
SILK VISTA BABY	Balt Extrusion	Thimar Al Jazirah Healthcare Co.	/Secure/CA/CaViewRecal	
VLP MINI-MOD 2.0MM STRAIGHT PLATE 6 HOLE	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Reusable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Adapter for handpiece, guided reusable, for guide	Thommen Medical AG	Samir Trading and Marketing CJSC.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	

Single-use devices

3M Reston Self-Adhering Foam Pads	3M Health Care Ltd	3M company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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AQUABEAM Handpiece	PROCEPT BioRobotics Corporation	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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CompoStop Platelet Storage Products	Fresenius Kabi Ltd.	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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Custom Tubing set	MAQUET Cardiopulmonary	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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Endwards Classic solution in bottle of 3ml	Meda Pharma S.p.A.	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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# EZ Derm Porcine Xenografts	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB		
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Intraluminal Staplers (ILS)	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
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# SensiCare PI Synthetic Polyisoprene Surgical Gloves	Medline Industries Inc....	Ikar Establishment		
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