

## NCMDR Weekly Update

23-Jul-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.

عزيري،  
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 23-Jul-19

Dear,  
 NCMDR team is pleased to inform you that **29** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **15-Jul-19** to **22-Jul-19** In order to view more details, click the links or attachments 

عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **29** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **15-Jul-19** إلى **22-Jul-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

HUDSON RDI NEONATAL ConchaSmart Breathing Circuit	Teleflex Medical..	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14</a>	
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### Assistive products for persons with disability


# SAMSOF Patient Lifts	DeVilbiss Healthcare LLC	FIVE DIMENSIONS CONSULTANCY OFFICE		
# Size 1 and 2 Marley Buggies	Rehabilitation Mfg Services Ltd RMS	N/A		
# TRANSWARMER Warming Infant Transport Mattresses.	Cooper Surgical, Inc.	Cure Development International Ltd		

### Diagnostic and therapeutic radiation devices

Fluorostar 7900 System	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
# Various CT Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		
# Visualase Cooled Laser Applicator System Tubing Sets	Medtronic SA	Medtronic Saudi Arabia		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Electro mechanical medical devices

corPatch easy pre-connected, GS defibrillation electrodes	Leonhard Lang GmbH	Teriag International	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14</a>	
EV1000 Clinical Platforms	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14</a>	
# SmartRelease Endoscopic Carpal Tunnel Release Handpieces	MicroAire Surgical Instruments.	Nogal Establishment		

### Healthcare facility products and adaptations

GETINGE Steam Steriliser .	Getinge Disinfection AB	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14</a>	
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### In vitro diagnostic devices

ADVIA Centaur®, ADVIA Centaur® XP, and ADVIA Centaur® XPT .	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14</a>	
Alinity c Lithium Reagent Kit ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14</a>	
cobas 8000 modular analyzer series (cobas 8000 ISE module, cobas c 701 module, cobas c 702 module, cobas c 502 module, cobas e 602 module, cobas e 801 module, cobas e 801 analytical unit), cobas 6000 analyzer series (cobas c 501 module, cobas e 601 module	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14575">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14575</a>	
FilmArray Gastrointestinal (GI) Panel.	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ImmunoCAP Tryptase Control .	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
ONLINE TDM Vancomycin Gen.3 (VANC3) ,	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a>	
ORTHO VISION® and ORTHO VISION® Max Analyzer ,	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">all.aspx?caid=4&amp;rid=14</a>	
QIAsymphony SP instrument (Software 5.0.3) .	QIAGEN Ltd	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">all.aspx?caid=10&amp;rid=1</a>	
VIKIA Malaria Ag Pf/Pan.	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	

### Medical software

STANLEY Healthcare Arial 54315 Network Manager environmental control, powered	Stanley Healthcare Solutions	N/A	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">all.aspx?caid=2&amp;rid=14</a> 581	
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### Non-active implantable devices

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (SAPIEN 3 Ultra Delivery System)	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">all.aspx?caid=8&amp;rid=14</a> 568	
Glace Screws 6 mm	Skulle Implants Corporation	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# Heavy Orthopedic Mallets	Mercian Surgical Supply	N/A		

### Ophthalmic and optical devices

HEYEX 2 image management components of SPECTRALIS PC Software .	HEIDELBERG ENGINEERING GmbH	Saudi Services & Health Care Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s a/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">all.aspx?caid=10&amp;rid=1</a> 4578	
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### Reusable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Kiwi Complete Vacuum Delivery System	CLINICAL INNOVATIONS, LLC	MEDICAL INNOVATIONS EST.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Single-use devices

#	Cardinal Health Jackson-Pratt 15 Fr and 19 Fr Round Fluted Drains ,	Cardinal-Health	MEDICARE DRUG STORE COMPANY		
	CRANI PACK	DeRoyal Industries, Inc.	Al-Jeel Medical & Trading Co. LTD	<a href="#">/Secure/CA/CaViewRecal</a>	
	IntraClude Intra-Aortic Occlusion Devices ,	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSC)	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	