



**Medical Devices Sector**

قطاع الأجهزة الطبية

**NCMDR**

**National Center for Medical Devices Reporting**

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

**NCMDR Weekly Update**

**28-May-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 المظلمة 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** 28-May-19

Dear,  
 NCMDR team is pleased to inform you that **48** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **20-May-19** to **26-May-19** In order to view more details, click the links or attachments 

عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **48** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **20-May-19** الى **26-May-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Assistive products for persons with disability

MediPress Segmental Garments	Compass Health Brands	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec</a>	
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### Dental devices

DEXIS Titanium Intraoral Sensor	KaVo Dental GmbH	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec</a>	
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### Diagnostic and therapeutic radiation devices

Centricity Universal Viewer with PACS-IW foundation 6.0 and Centricity PACS-IW	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=14343">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=14343</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
EKOS Control System 4.0	EKOS Corp	Arabian Trade House Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
GAMMA SUPII	CLERAD	Almarfa Medical	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
InterStim Therapy Programmer Compatibility	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
NeuViz 64 Multi-slice, 128 Multislice and 16 Essence Multislice CT Scanner System.	Neusoft Medical Systems	Al Afandi Establishment	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14341">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14341</a>	
Olea Sphere	OLEA MEDICAL S.A.S	N/A	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
Senographe Pristina with Serena	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	

### Electro mechanical medical devices


Arterial Blood Sampling System	CODAN Medizinische Geraete GmbH & Co	Alwan Alnoor Trading Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Defibrillation electrode Mindray MR62, Weinmann defibrillation electrodes	Leonhard Lang GmbH	Teriag International	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14319">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14319</a>	
# ENSEAL X1 Curved Jaw Tissue Sealers	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# LSB Style Anchor Bolts	Ad-Tech Medical Instrument Corp	Al-Nozha Medical Est		
M200 Fall Monitoring System	Stanley Healthcare Solutions	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Sinapi Chest Drain	napi Biomedical (Pty) L	L Medical Development Foundati	<a href="#">/Secure/CA/CaViewRecal</a>	
# Waterlase Laser Tips	Biolase, Inc	FAROUK, MAAMOUN TAMER & COMPANY		

### In vitro diagnostic devices

ABL800	Radiometer America Inc	Salehiya Trading Est.	<a href="#">/Secure/CA/CaViewRecal</a>	
Alinity c Complement C3, C4, Alinity c Immunoglobulin A, G, M, Alinity c Apolipoprotein A1, B, Alinity c Haptoglobin, Alinity c Transferrin Reagent Kits	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14314">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14314</a>	
Alinity ci-series System Control Module	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
ARCHITECT Complement C3, C4, Immunoglobulin A, G, M, Apolipoprotein A1, B, Haptoglobin, Transferrin	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	
AUTION HYBRID AU-4050	ARKRAY GLOBAL business, Inc	Enmaeyat Trading Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	
CELL-DYN Emerald; Emerald Diluent Tubing	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	
Cobas infinity central lab IT solution	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	
i-STAT BNP and CK-MB Control and Calibration Verification Control fluids	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14315">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14315</a>	
Mentype AMLplexQS	Biotype Diagnostik GmbH	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	
# Pancreatic Amylase Reagents	Randox Laboratories Ltd.	Bio Standards	Check email	
Power Express Sample Processing System	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14313</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Thio Med w/Dex, Hem, Vit, K (7ml) and (5ml)	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Thio Med w/o Ind, w/Dex	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# UniCel DxH 800 and UniCel DxH 600 Coulter Cellular Analysis System	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD		
VIDAS NT-proBNP2	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Laboratory equipment

Hemoglobin A1c Calibrators	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Medical software

Centricity PACS-IW versions 3.6.0 through 3.7.3.9 SP1, SP2, SP3 and 3.7.3 SPa10	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14344">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14344</a>	
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### Non-active implantable devices

Orbera Intragastric Balloon System and BIB Intragastric Balloon System	Apollo Endosurgery Inc.	Al-Nozha Medical Est	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14333">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14333</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Rim Platte, 10-Loch, Links, PRS RX System, Rim Plate	I.T.S. GmbH	Medical Regulations Gate	<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>	

### Reusable devices

Membrane Changers and their Inserts	SenTec AG.	Medical regulations gate	<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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OLYMPUS EVIS EXERA and EVIS LUCERA DUODENOVIDEOSCOPE	Olympus	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14318">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14318</a>	
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### Single-use devices


# Covidien Endo GIA Articulating Reloads with Tri-Staple Technology	Medtronic SA	Medtronic Saudi Arabia		
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ENFit NGP and Ryles Nasogastric Feeding Tubes	Medicina	Al Hammad Medical Services	<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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ICSI MICROPIPETTE	Cooper Surgical, Inc.	Cure Development International Ltd	<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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Integra Flowable Wound Matrix	Integra LifeSciences	Bio Standards	<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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# IntraClude Intra-Aortic Occlusion Devices	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	Check email	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Microtainer Tubes	Becton Dickinson & Co. (E	Becton Dickinson B.V.		
Neomem	Collagen Matrix, Inc.□	Asnan Medical Services	<a href="#">/Secure/CA/CaViewRecal</a>	
Portico Solo Re-Collapsible Access System	St. Jude Medical Inc.,	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
ThermaCare Lower Back & Hip Heatwraps	PFIZER CONSUMER HEALTHCARE	Ahmed Mohammed Abdulwahab Naghi & Sons	<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>	
Various Gastric Tubes and Catheters	Ivor Shaw Limited As Peninne Healthcare	Advance Nfood Medical Company	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# WaveLinQ 4 Fr EndoAVF Systems	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	Check email	