



# NCMDR

**National Center for Medical Devices Reporting**

**المركز الوطني لبلاغات الأجهزة والمنتجات الطبية**

**NCMDR Weekly Update**

**26-Mar-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** 26-Mar-19

Dear, NCMDR team is pleased to inform you that **43** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **18-Mar-19** to **24-Mar-19** In order to view more details, [click the links or attachments](#) 


عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **43** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **18-Mar-19** الى **24-Mar-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Anaesthetic and respiratory devices

Aisys CS2 anesthesia devices	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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Gibeck HME Filter + Catheter Mount, RUSCH Connectors Bulk for Breathing Circuit	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14046">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14046</a>	
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# Zeus IE Anesthesia Workstations	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.		
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### Diagnostic and therapeutic radiation devices

Cios Alpha VA20	SIEMENS	Siemens Medical Solutions	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Digital Linear Accelerators of type ARTISTE, ONCOR and PRIMUS running	Siemens Medical Solutions	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14037">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14037</a>	
Elekta Unity.	Elekta Inc	Medical Regulations Gate	<a href="#">/Secure/CA/CaViewRecal</a>	
Innova IGS 6 and Innova IGS 630 Systems	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14023">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14023</a>	
Treatment Planning and Delivery Software (TPDS) in use with the MRIdian System	Viewray Incorporated	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14023">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14023</a>	

### Electro mechanical medical devices

A610 DBS Activa Clinician Programmer Application.	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1</a>	
Connection Lead SP (12V) for Infusomat Space, Infusomat Space P and Perfusor Space	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14053">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14053</a>	
# enFlow IV Fluid and Blood Warmers	Vyair Medical	Spectromed		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Infinity Acute Care System (IACS) and Infinity M540 Stand Alone Monitor	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	

### Healthcare facility products and adaptations

PREVIN- MINI-TAD & MIKRO-TAD	PREVOR GmbH	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	
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### In vitro diagnostic devices

Albumin BCP (ALBP)	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	
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ARCHITECT Hemoglobin A1c (HbA1c) Reagent	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14031">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14031</a>	
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BD Phoenix™ PMIC/ID-69 Panel	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	
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cobas 8000 modular analyzer series & cobas pro integrated solutions, Procell II M	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14031">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14031</a>	
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DxA 5000 Automation System.	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	
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Echinococcus IgG ELISA, RE56201	IBL International GmbH..	Samir Trading and Marketing CJSC.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14039</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
GXT NA Extraction Kit	Hain Lifescience GmbH	Bio Alternatives Establishment	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# Lactose intolerance quick test	BIOHIT OYJ	Qualb Al-Hayat Est.		
Leica Biosystems Cryostats.	Leica Biosystems Nussloch GmbH	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
MAS ChemTRAK H Assayed Control Level 3	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
recomLine Helicobacter 2.0 IgG/IgA	Mikrogen GmbH	WAREED ALHAYAT	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14054">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14054</a>	
VITROS• XT 7600 Integrated System	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	


### Laboratory equipment

MicroScan WalkAway Instrument	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
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### Medical software

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
syngo CT Cardiac Function and Planning	Siemens Medical Solutions	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Non-active implantable devices

# 14 Fr SLX Double Lumen Full Trays	Medcomp	Farabi Trading Establishment		
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balanSys Femur Holder	Mathys.	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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Bohrloch Reservoir Set, Ventricular Catheter	Christoph Miethke GmbH & Co. KG	Excellent Care Medical Co. Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec.all.aspx?caid=6&amp;rid=14">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec.all.aspx?caid=6&amp;rid=14</a>	
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LactoSorb System 14mm Rapid Flap	Zimmer, INC....	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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Mod. rev. neck lateral with screw 60	Mathys.	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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# REEF Cementless Metaphyso-Diaphyseal Femoral Stems	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited		
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### Ophthalmic and optical devices

IMAGENet 6 Ophthalmic Data System	Topcon Medical Laser Systems	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Single-use devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Certifix® Quattro ,	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# Covidien Endo Clinch II and Endo Grasp Auto Suture Graspers	Medtronic SA	Medtronic Saudi Arabia		
MAJ-209 Single-Use Suction Valve	Olympus	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
# Nexiva Closed IV Catheter Systems	BD Biosciences	Becton Dickinson B.V.		
Plain and Chromic Gut Absorbable Surgical Sutures	CP Medical Inc	N/A	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14</a>	
VAMP Optima Blood Sampling 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>	
VICRYL Suture and VICRYL Plus Suture Products	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
VICRYL Suture and VICRYL Plus Suture Products	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	