



# NCMDR

**National Center for Medical Devices Reporting**

**المركز الوطني لبلاغات الأجهزة والمنتجات الطبية**

**NCMDR Weekly Update**

**26-Feb-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-Feb-19

Dear,  
 NCMDR team is pleased to inform you that **42** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **18-Feb-19** to **24-Feb-19** In order to view more details, [click the links or attachments](#) 

عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **42** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **18-Feb-19** الى **24-Feb-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

Adapta Dual Chamber Pacemakers ,	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Anaesthetic and respiratory devices

HAMILTON-G5/ HAMILTON-S1 ventilator unit	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Assistive products for persons with disability

# Combi Loop Slings	Arjo Huntleigh	Al-Faisaliah Medical System		
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### Dental devices

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
InterActive Precision IO Scan Adapter	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# OVC3 Crown Refills	Rhodium Ltd	N/A		

### Diagnostic and therapeutic radiation devices

Digital Angiography System Trinias	Shimadzu Medical Systems.	Al Afandi Establishment	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Mobile X-Ray System MobileDaRt Evolution Handle	Shimadzu Medical Systems.	Al Afandi Establishment	<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>	
MultiDiagnost Eleva with Flat Detector, Cardio Vascular-Allura Centron and multiple Allura Xper products	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13907">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13907</a>	
Multiple SOMATOM CT Scanners - syngo CT VB10A with Option Dual Spiral Dual Energy ,	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13913">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13913</a>	
# StentBoost Software	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# SureSigns VS & VM Monitors, and View Station (VSV)	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.		

TrueBeam Radiotherapy System with Visual Coaching Device or EDGE or VitalBeam.	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13901">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13901</a>	
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UROSKOP OMNIA and UROSKOP OMNIA MAX	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13</a>	
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### Electro mechanical medical devices

Alaris VP Plus with Guardrails	Becton, Dickinson And Company	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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AMIA &Kaguya Automated Peritoneal Dialysis System	Baxter Corp Canada	Baxter AG	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13</a>	
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COBRA FUSION 50 and 150 Ablation System	AtriCure	Saudi Sicli Company	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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# Covidien Force TriVerse Electrosurgical Device 10-Foot Cords	Medtronic SA	Medtronic Saudi Arabia		
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Duodenovideoscope TJF-160VR ,	Olympus	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
GRP handles with and without ratchet	VOMED Volzer Medizintechnik GmbH & Co. KG	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13911">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13911</a>	
Obturator, short cone 7" and long cone 10" (an accessory to the Flex Rectoscope)	Medrobotics Corporation	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13911">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13911</a>	

### Healthcare facility products and adaptations

EMS Stretcher	Bucher Leichtbau AG	N/A	<a href="#">/Secure/CA/CaViewRecal</a>	
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### In vitro diagnostic devices

#	Access Thyroglobulin Antibody II Reagents	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd		
#	BioPlex 2200 HIV Ag-Ab Kits	Bio-Rad Laboratories Inc	Al-Jeel Medical & Trading Co. LTD		
	BRAHMS uE3 KRYPTOR	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
	CELL-DYN Emerald ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
#	Dual Luciferase Reporter Assay System Kits	Promega Corpopration	Bio Standards		

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Immunoassay Premium, Immunoassay Premium Plus, Liquid Immunoassay Premium	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=13904">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=13904</a>	


VITEK 2 ASTN351 Test Kit	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893</a>	
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VITROS Immunodiagnostic Products Myoglobin Calibrators	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893</a>	
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### Medical software


Zenzy 2.46 software	Dr. Heni Software GmbH & Co. KG	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13893</a>	
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### Non-active implantable devices



# 15 g SIGNAFUSE Bioactive Bone Graft Putty	Bioventus LLC	Zimmo Trading Establishment.		
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Bard Lifestream Balloon Expandable Vascular Covered Stent ,	C R Bard Inc	C.R. BARD Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13898">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=13898</a>	
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ENDURO SPECIAL KEY TIB.LOCK.RING F1/10MM	Aesculap	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13898">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13898</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Genius Knee Cemented CR Femoral Component	Signature Orthopaedics	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13</a>	
NSE PTA Balloon Catheter GDM01	Goodman Co., Ltd.	Medical Solutions & Ideas	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13</a>	
# PowerPort isp MRI Implantable Ports	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia		
Vanguard Knee System Series-A Standard Patella	Zimmer, INC....	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13</a>	

### Single-use devices

Ardo Sterile Tulips Nipple Shields, Medium and Large	Ardo medical AG	Medical supplies & Services Co.Ltd Mediserv	<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>	
# BD 3 mL Safety-Lok Syringes Contained in Presource Kits	Cardinal-Health	MEDICARE DRUG STORE COMPANY		
Pilling COOLEY SUMP-SUCTION TUBE	Teleflex Medical□	Medical Technology Trading Company	<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>	
# Portex Blue Line Ultra Tracheostomy Tube Inner Cannulae	Smiths Medical International Limited	almadar medical Est.		

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Terumo Needle and Terumo Needle Neolus ,	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	