

## NCMDR Weekly Update

07-Aug-19

Dear,  
NCMDR team send a weekly update every week containing the latest Field Safety Corrective Actions (FSCA) of medical devices/products on SFDA website.

عزيزي،  
يقوم المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بإرسال تقرير اسبوعي عن آخر الإجراءات التصحيحية للسلامة الميدانية 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 الإجراءات التصحيحية للسلامة الميدانية.
- التواصل مع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ومع الممثل القانوني للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إجراءات التصحيحية للسلامة الميدانية

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 FSCA's indicates that the source of this FSCA is ECRI.
- Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

- الإجراءات 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 إجراء التصحيح للسلامة الميدانية من منظمة (ECRI).
- لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.

**NCMDR Weekly Update 07-Aug-19**

Dear,  
 NCMDR team is pleased to inform you that **41 new FSQA/ for medical devices and products posted on SFDA website for the period of 29-Jul-19 to 04-Aug-19** In order to view more details, click the links or attachments 

عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **41** إجراءات تصحيحية للسلامة الميدانية للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **29-Jul-19** الى **04-Aug-19** ،  
 لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
---------------	--------------	--	------	-----------------

**Active Implantable Devices**

Powerport Cleavue Slim Implantable Port	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
---	-----------------------------------	------------------------	---	--

**Anaesthetic and respiratory devices**

Capiox NX19 Oxygenator	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
Single Luman Conserver	Inovo, Inc	N/A	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	

**Assistive products for persons with disability**

Maximum Pelvic Trainer	Ralston Group	N/A	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
---------------------------	---------------	-----	---	--



**Dental devices**



KaVo RONDOflex Powder 27µm 1000g to be used with the KaVo RONDOfLEX plus 360 air abrasion system ,	Kaltenbach & Voigt GmbH	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14618">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14618</a>	
--	----------------------------	--------------------------------------	---	--

**Diagnostic and therapeutic radiation devices**

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Biograph mCT and mCT Flow systems running PETsyngo VG70A .	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14606">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14606</a>	
MAMMOMAT Revelation VC10 with Biopsy Option .	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14606">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14606</a>	
SOMATOM Definition Edge , SOMATOM Definition AS, SOMATOM Definition Flash, with syngo .	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14607">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14607</a>	

### Electro mechanical medical devices




CSM-1500 & CSM-1700 Monitoring Systems	Nihon Kohden Corporation..	FAROUK, MAAMOUN TAMER & COMPANY	<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>	
# da Vinci X, Xi, and SP Surgical Systems	Intuitive Surgical Inc	Gulf Medical Co.		
# Hemospray Endoscopic Hemostatic Agent Delivery Systems	Cook Medical Europe Limited,	ARABIAN MEDICAL & PHARMACEUTICAL CO.		
motion cycle 600 med .	emotion fitness GmbH & Co. KG	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14625">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14625</a>	
Norm-O-Temp Hyperthermia System, MICRO-TEMP LT System, Blanketrol II Hyper-Hypothermia System, Blanketrol III Hyper-Hypothermia System and CoolBlue Hyper-Hypothermia System .	Cincinnati Sub-Zero Products Inc	Al Shoumoukh Trading for Technical and Medical Supplies	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14625">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14625</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
PulsioFlex Monitor	GETINGE US SALES LLC	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# PulsioFlex Monitor	GETINGE US SALES LLC	N/A		
Rusch EasyCath Kit	Teleflex Medical..	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Spectra Optia Apheresis System	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
# Telefunken HR1 and FA1 Automated External Defibrillators	Defiteq International	N/A		
Versa - Kath Mini Kit, with plastic L.O.R Syringe 12g X 12in (30.5 cm)	Epimed International, Inc.	N/A	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14</a>	

### Healthcare facility products and adaptations

EZTest H202 Biological Indicators	Mesa Laboratories, Inc.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
-----------------------------------	-------------------------	-------------------------------------	---	--

### In vitro diagnostic devices

# ACHRab RIA kits.	RSR Ltd	N/A		
Autostat II Rheumatoid Factor IgM ELISA	Hycor Biomedical Inc.	N/A	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a>	
Coombs-Control IgG 1x10 ml	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# CTS Essential 8 Media	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv		
# PrivaPath Personal Health and Sexual Health Tests	Mckesson Information Solutions LLC	N/A		

### Medical software

SSL Certificate Expiration	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
----------------------------	------------------------	--	---	--

### Non-active implantable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
DJO Surgical	Encore Medical, Lp	AL EWAN MEDICAL COMPANY	<a href="#">/Secure/CA/CaViewRecal</a>	
# Erisma-LP Posterior Fixation Systems	Clariance Inc	N/A		
Orbera Intra-gastric Balloon System and BIB Intra-gastric Balloon System	Apollo Endosurgery Inc.	Al-Nozha Medical Est	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14630">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14630</a>	
PEEK Cervical Cages and PEEK Lumbar Cages	Medicrea International.	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# Textured Breast Implants and Tissue Expanders	Allergan services international Limited	Cigalah Group		
<b>Single-use devices</b>				
# 10 Fr Oxygen Catheters	ASSAmed GmbH	N/A		
A&E Medical Corp. UltraFlex	A&E Medical Corporation.	Raz medical	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Acuject Variable Injection Needle	Cook Medical Europe Limited,	ARABIAN MEDICAL & PHARMACEUTICAL CO.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# Centurion Alaris Pump Infusion Sets	Medline Industries, Inc.	Cure Development International Ltd		
# Endotrac Hook/Triangle Blade Kits	Stryker Instruments.	Zimmo Trading Establishment.		
# MED-SEMI RIGID Liner Systems	Medline Industries Inc.....	Spectromed		
# Premier Convex Tape-Bordered Urostomy Pouches .	Hollister Inc	FAROUK, MAAMOUN TAMER & COMPANY		
Sheridan Endotracheal Tube	Centurion Medical Products	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# Sterile CoFlex Products .	Andover Healthcare Inc	N/A		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
VITALE Silicon Foam Dressings 4"x4"	CellEra LLC	N/A	<a href="https://ncmdr.sfd.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfd.gov.s/Secure/CA/CaViewRec</a>	