

## NCMDR Weekly Update

15-Sep-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 15-Sep-19

Dear,  
 NCMDR team is pleased to inform you that **57** new FSQA/recalls for medical devices and products posted on SFDA website for the period of 09-Sep-19 to 15-Sep-19 In order to view more details, click the links or attachments 


عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **57** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة 09-Sep-19 إلى 15-Sep-19 ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

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

Atomizer – EZ Spray ,	Alcove Medical Inc.	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Medisorb Cannister 0.8kg ,	Vyaire Medical, Inc..	Bio Standards	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	

### Assistive products for persons with disability

Epidural Positioning Device (EPD)	Pivotal Health Solutions	N/A	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
# Knight Scooters	rive DeVilbiss Healthca	DIMENSIONS CONSULTANCY OF		
munevo DRIVE	munevo GmbH	N/A	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	

### Dental devices

DIATECH, ROUND END TAPER	Coltene Whaledent Inc.	Asnan Medical Services	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Drill Extension for Astra Tech Implant System	DENTSPLY International	Branch of DENTSPLY International Inc	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	

### Diagnostic and therapeutic radiation devices


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Atellica UAS 800 Analyser and Atellica 1500 Automated Urinalysis System. ,	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14750">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14750</a>	
Flexavision F3	imadzu Medical System	Al Afandi Establishment	<a href="#">/Secure/CA/CaViewRecal</a>	
Fujifilm FDR Go Plus mobile Xray system	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Electro mechanical medical devices

AngioDynamics VenaCure EVLT NeverTouch Procedure Kit	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	<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>	
C3 CryoProbe 2.1 mm sharp ,	Inomed Medizintechnik GmbH	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
CentriMag Motors	Thoratec Corp	Arabian Trade House Est.	<a href="#">/Secure/CA/CaViewRecal</a>	
Getinge MCC Flow i Disposable CO2 absorber	Getinge Disinfection AB	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
HeartStart MRx	Philips Healthcare	hilips Healthcare Saudi Arabia Ltd	<a href="#">/Secure/CA/CaViewRecal</a>	
Lemaitre Aortic Occlusion Catheter	LeMaitre Vascular GmbH	Majal Care for Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
# Model 96102 Xhibit Central Stations .	Spacelabs Healthcare Inc	Gulf Medical Co.		
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=14788">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14788</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
SCP Control panel (Subset)	LivaNova PLC	cigalah group	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	

### Healthcare facility products and adaptations

#	Endure Foam Hand Soap ,	Ecolab Inc	Al Hammadmedical Services		
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### In vitro diagnostic devices

Atellica IM anti-CCP IgG (aCCP) and Pregnancy-Associated Plasma Protein-A (PAPP-A)	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14758">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14758</a>	
BD FACSLyric Flow Cytometer .	BD Biosciences	Becton Dickinson B.V.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
COBAS AmpliPrep/COBAS TaqMan HCV Quantitative Test, v2.0 .	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14748">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14748</a>	
Dario Blood Glucose Tracker app .	LabStyle Innovations Ltd	N/A	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
LBgard Blood Collection Tube	Biomatrica, Inc.	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
NK044.OPT-Optilite C-Reactive Protein Reagent.	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14</a>	
PreImpScreen PoIB (13 16 18 21 22)	Kreatech Biotechnology BV	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	
REMISOL Advance. ,	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Salivary Estrone ELISA	DRG Instruments GmbH	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Various Assays ,	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/a/Secure/CA/CaViewRec</a>	

### Laboratory equipment

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
BD Kiestra Inoqula Software Version 20.3.	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Non-active implantable devices

Powerflex PRO PTA balloon dilation ,	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
SYMBOL CUP DM: SCREW	Dedienne Santé	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Threaded Offset Cup Impactor	Exactech	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Triathlon Orthopaedic Devices	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Vanguard XP-CR Tibial Tray ,	Zimmer, INC....	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Reusable devices

Integra Jarit Gemini Clamp 9 inch	Integra LifeSciences	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Intubation Fiberscope	Karl Storz Endoscopy UK Ltd	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
TheraBead Compress Cervical and TheraBead Compress STD ,	Briggs Healthcare	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec/all.aspx?caid=10&amp;rid=14753">all.aspx?caid=10&amp;rid=14753</a>	

### Single-use devices

Arterial Catheter Mini Kit 20ga x 6"	Argon Medical Devices	Al Amin Medical Instruments Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
AV-SET B-R & AV-Set SRB-R	Fresenius Medical Care.	Fresenius Medical Care GmbH	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Barrier Sets.	Molnlycke Health Care A	Branch of Molnlycke Health Care A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
CUTISOFT PACK Catheter Change Set	BSN Medical	Alhaya medical co.	<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
Euphora and Solarice Semi-Compliant Rapid Exchange Balloon Dilatation Catheters .	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14752">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14752</a>	
# Euphora and Solarice Semi-Compliant Rapid Exchange Balloon Dilatation Catheters .	Medtronic SA	Medtronic Saudi Arabia		
Hudson RCI Sheridan LTS	Teleflex Medical..	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
LemonPrep 114gm tubes ,	Mavidon Medical Products	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# LifeCare PCA Sterile Empty Vials ,	ICU Medical, Inc	AL-KAMAL Import		
MAJ-209 Single-Use Suction Valve	Olympus	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
MediTainer, MediBowl, MediDuo	Omni-Pac Ekco GmbH	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Prima Supervac Fingerswitch Pencils with Smoke Evacuation Tubing ,	Prima Medical Ltd	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14755">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14755</a>	
Rocket FBS Amnioscopes	Rocket Medical	Modern Quality Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
# Rusch DispoGrip Single-Use Standard Laryngoscope Handles	Teleflex Medical..	Gulf Medical Co.		
SPROTTE lumbal with Introducer	PAJUNK GmbH Medizintechnologie	Kafou Medical Co.,	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Terumo Cardiopulmonary Extracorporeal Tubing Set Modular Perfusion Blood Circuit	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14738">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14738</a>	
Titan Gel Serum Protein Control (SPE Control)	Helena Biosciences Europe	Fuad Abdul Jalil Al Fadhli & Sons	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14776">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14776</a>	
Various Convex Two-Piece Skin Barriers  Natura, Surfit and Combihesive Wafers	ConvaTec	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14776">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14776</a>	