



Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

29-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.

عزيمي،  
يقوم المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بإرسال تقرير اسبوعي عن آخر اشعارات إنذارات السلامة / الاستدعاءات للأجهزة والمستلزمات الطبية المنتشرة 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 29-Sep-19**

Dear, NCMDR team is pleased to inform you that **35** new FSCA/recalls for medical devices and products posted on SFDA website for the period of **22-Sep-19** to **26-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 **35** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **22-Sep-19** إلى **26-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**

#	NIPPY Ventilator Breathing Circuits	BREAS Medical AB A GE Healthcare Co	LEADER HEALTHCARE SAUDI ARABIA		
	Rusch TracFlex Plus Phonation Set, Cuffed; Rusch TracFlex Plus Set, cuffed; TracFlex Plus PDT Set; Ruschcare TracFlex Plus Phonation Set, Cuffed	Teleflex Medical..	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14850">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14850</a>	

**Assistive products for persons with disability**

Selected Behind-the-Ear hearing aids	GN ReSound A/S	Mada Hearing Company Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850</a>	
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**Diagnostic and therapeutic radiation devices**

1.5T Express Head Neck Array Coil Surface Temperature	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850</a>	
DigitalDiagnost C50	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14850</a>	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Forte Gamma Camera Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
iLab Polaris Multi-Modality Guidance System	Boston Scientific Ltd	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
MOSAIQ	Elekta Inc	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Electro mechanical medical devices

Arrow QuadLumen Central Venous Catheterization Kit, ARROWgard Blue PSI Kit CathGard	Arrow International Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14842">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=14842</a>	
IntelliVue 1.4 GHz Remote Antenna Used with Philips MX40 Monitors	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<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>	
MSI Biopsy Instruments	adeor Medical AG	Isam Economic Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Patientcable for ECG Amplifier BT-12	Medset Medizintechnik GmbH	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
Philips HeartStart FRx and HS1 OnSite Automated External Defibrillators (AEDs)	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14832">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=14832</a>	
Spectra Optia Apheresis System	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>	
Steelco Endoscope Dryers	Steelco SpA.	Insight Medical Systems	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### In vitro diagnostic devices

Alinity i STAT Myoglobin Reagent Kit	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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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
D-cards DC-Screening II	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
Elecsys Anti-CCP assay used in cobas e 411 / 601/ 602/ 801 systems	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14856">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14856</a>	
EMBRYOLOGY HEATED PLATE WITHIN THE RI WITNESS	CooperSurgical Inc..	ATTIEH MEDICO LTD	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=14</a>	
HemoCue 201 DM - DMS Software CD and HemoCue Glucose 201 DM RT System	HemoCue AB	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14841">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=14841</a>	
Intermittent Slide Dispense Issues with VITROS® Chemistry Products Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14830">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=14830</a>	
# Kappa (EP171) Rabbit Monoclonal Antibody Reagents ,	Cell Marque	medical business Center		
Multigent Lithium Assay, Alinity c Lithium Reagent Kit	SENTINEL CH. SpA	Medical supplies & Services Co.Ltd Mediserv	<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>	
# ORTHO VISION® and ORTHO VISION® Max Analyzer ,	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.		
# Oxoid 4 mm Depth Iso-Sensitest Agar ,	Oxoid Ltd Div Thermo Fisher Scientific Inc	Medical supplies & Services Co.Ltd Mediserv		
ROTEM ex-tem	TEM Innovations GmbH	Alyam Technical Est.	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
V-Twin	Vital Scientific N.V.	N/A	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	

### Non-active implantable devices

ATOK Shoulder Anchor ,	Signature Orthopaedics	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
INNOTERE Paste-CPC, 3ml	InnoTERE GmbH	ELAF MED LIMITED COMPANY	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
QuickGraft	eleetal Transplant Founc	ProMedEx	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
RT-PLUS MODULAR FEMORAL BLOCK	Smith & Nephew inc	Smith & Nephew inc	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a> <a href="a/Secure/CA/CaViewRec">a/Secure/CA/CaViewRec</a>	
Zenith Branch Iliac Endovascular Graft (ZBIS) - Patient Card	Cook Medical	Majal Care for Trading Est.	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a> <a href="a/Secure/CA/CaViewRec">a/Secure/CA/CaViewRec</a> <a href="all.aspx?caid=6&amp;rid=14">all.aspx?caid=6&amp;rid=14</a>	

### Single-use devices

# Conquest 40 PTA Dilatation Catheters	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia		
HEMASHIELD PLATINUM Woven Double Velour Vascular Graft	Maquet Cardiovascular,LLC.	Saudi Sicli Company	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a> <a href="a/Secure/CA/CaViewRec">a/Secure/CA/CaViewRec</a> <a href="all.aspx?caid=2&amp;rid=14">all.aspx?caid=2&amp;rid=14</a> <a href="844">844</a>	
Medline International Sterile Absorbent Cotton O.R Towels that are included in AreRoyal procedure packs	ArcRoyal	N/A	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a> <a href="a/Secure/CA/CaViewRec">a/Secure/CA/CaViewRec</a> <a href="all.aspx?caid=6&amp;rid=14">all.aspx?caid=6&amp;rid=14</a> <a href="839">839</a>	