



# NCMDR

**National Center for Medical Devices Reporting**

**المركز الوطني لبلاغات الأجهزة والمنتجات الطبية**

**NCMDR Weekly Update**

**15-Jan-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** 15-Jan-19

Dear,  
 NCMDR team is pleased to inform you that **25** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **07-Jan-19** t **13-Jan-19** In order to view more details, [click the links or attachments](#) 

عزيمي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **25** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **07-Jan-19** الى **13-Jan-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

Pulsante SPG Microstimulator System.	Autonomic Technologies Inc. (ATI)	N/A	<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

# Medline-Labeled Sterile Water Manufactured by Smiths Medical	Medline Industries, Inc.	Cure Development International Ltd		
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VentStar Disposable Breathing Circuits	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Dental devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Enamelast Cool Mint/OT Varnish 5 NaF Mint	ultradent products INC.	DENTAL ERA EST.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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>	
octenidol md mouthwash	Schülke & Mayer GmbH	Life Pulse Medical Co.	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	

### Diagnostic and therapeutic radiation devices


Eclipse Treatment Planning System..	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
IONTRIS.	SIEMENS	Siemens Medical Solutions	<a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a>	
Merge Eye Station Excessive Electrical Output	Merge Healthcare Corp.	N/A	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	

### Electro mechanical medical devices


Baha 5 Sound Processor Tamper-proof battery door 3	Cochlear AG	ABDULREHMAN AL GOSAIBI GTB	<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>	
Gentlelase PRO	Candela Corporation	Imdad Medical Business Company Ltd.	<a href="https://ncmdr.sfda.gov.sa">https://ncmdr.sfda.gov.sa</a>	
MiniMed™ Paradigm™ Veo™ Insulin Pump	Medtronic SA	Medtronic Saudi Arabia	<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
Philips PageWriter TC Cardiographs (TC20/30/50/70) ,	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13</a>	

Proctoscope.	Wing Plast AB	N/A	<a href="#">/Secure/CA/CaViewRecal</a>	
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# VENTURI Negative-Pressure Wound Therapy Dressings .	Talley Healthcare Services	Dawha Medical		
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### In vitro diagnostic devices

# ARCHITECT Magnesium Reagents	Abbott	Medical supplies & Services Co.Ltd Mediserv		
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Panocell-16 Kit .	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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VITROS MicroWell Assays, Folate, Free PSA	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### Non-active implantable devices

Mobi-C Cervical Disc Prosthesis	Zimmer, INC....	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
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Nellix, Endovascular Aneurysm Sealing System..	Endologix international holding B.V.	Tart Medical	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=13">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&amp;rid=13</a>	
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MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
Revision femoral neck H60mm lateralised + Screw ,	Limacorporate S.p.a.	N/A	<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>	

### Single-use devices

#	Catheters Contained in Rectus Sheath Sets ,	Mediplus Ltd.	N/A		
#	Medex High-Pressure Stopcocks ,	Smiths Medical International Limited	almadar medical Est.		
	UNIMED Needles	Unimed S.A.	N/A	<a href="#">/Secure/CA/CaViewRecal</a>	
#	Wire Guides Contained in Various Trays	Cook Inc,	Majal Care for Trading Est.	