



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

12-Mar-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 12-Mar-19

Dear,
 NCMDR team is pleased to inform you that **29** new FSQA/recalls for medical devices and products posted on [SFDA website](#) for the period of **04-Mar-19** to **10-Mar-19** In order to view more details, [click the links or attachments](#) 

عزيمي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **29** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **04-Mar-19** الى **10-Mar-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

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

Hamilton-C6	HAMILTON MEDICAL AC	Daleel Al Raeda Trading Est	/Secure/CA/CAViewRecal	
PARI LC SPRINT Tracheo	PARI	electronic technicians est	https://ncmdr.sfda.gov.s	


Assistive products for persons with disability

Sara 3000, Tenor, Minstrel	Arjo Huntleigh	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.s	
Sara Plus Lift	Arjo Huntleigh	Al-Faisaliah Medical System	/Secure/CA/CAViewRecal	
Strap Gripper	Liko AB	Medical regulations gate	/Secure/CA/CAViewRecal	

Dental devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
3.4mm Certain BellaTek Abutment, ILDAT3	Biomet 3i Inc	Asnan Medical Services	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	


Diagnostic and therapeutic radiation devices


# MATRIX DS Data Stations Used with XION Endoscopy Systems	Xion GmbH	ATTIEH MEDICO LTD		
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StealthStation S7 and i7 Systems with Synergy Cranial StealthStation Cranial Software	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13978	
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Velocity Advanced Imaging [AI], Velocity Advanced Imaging Solutions [AIS] or VelocityGRID.	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=13975	
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Electro mechanical medical devices



# enFlow IV Fluid and Blood Warmers	Vyair Medical	Spectromed		
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# HydroMARK Breast Biopsy Markers	Mammotome	N/A		
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Meddtronic Model 37751 Recharger included in Model 37651 Charging System	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13974	
# Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor ,	Radiometer America Inc	Salehiya Trading Est.		
Stryker Sustainability Solutions (SSS)	Stryker Sustainability Solutions	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13970	
# T34 Ambulatory Syringe Pumps .	Caesarea Medical Electronics Ltd	N/A		
In vitro diagnostic devices				
Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13970	
Alinity i Processing Module and Alinity c Processing Module	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13971	
ImmunoCAP ISAC slgE 112	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=13971	


MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Level 2 Urinalysis Controls	Randox Laboratories Ltd.	Bio Standards		
Phoenix ASTs Indicator	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.s	
Phoenix ASTs Indicator	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.s	

Non-active implantable devices

# Small Diameter Cement Plug Inserters	Zimmer, INC....	Medical Regulations Gate		
# Stress Urinary Incontinence and Pelvic Organ Prolapse Surgical Mesh Products	C R Bard Inc	C.R. BARD Saudi Arabia		

Single-use devices

Cannula needle.	Applimed SA	N/A	/Secure/CA/CaViewRecal	
# ChemoLock Vial Spikes	ICU Medical, Inc	AL-KAMAL Import		
# ETHIBOND EXCEL Sutures	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited		
# Laparotomy Sponges	Medical Action Industries Inc	Saudi Medical Services SMS		

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Maquet Cardiopulmonary Pre-Bypass Filters used for Customised Tubing Packs ,	MAQUET Cardiopulmonary GmbH	Medical Elements		
Pulmonary Vein Ablation Catheter GOLD (PVAC GOLD)	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	