



NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

09-Jul-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 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 09-Jul-19

Dear,
 NCMDR team is pleased to inform you that **35** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **01-Jul-19** to **07-Jul-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 **01-Jul-19** إلى **07-Jul-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributer	Link	Affected Yes/No
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Diagnostic and therapeutic radiation devices

# Models WM-NP2 and WM-DP2 Mobile Workstations Used with Nurse Control Panel Arm	Olympus	Salehiya Trading Est.		
PROBEAT-V	Hitachi, Ltd. Healthcare	UK, MAAMOUN TAMER & COME	/Secure/CA/CAViewRecal	
SOMATOM Force, SOMATOM Definition AS, SOMATOM Definition Edge, SOMATOM Definition Flash, SOMATOM Drive, SOMATOM Confidence, SOMATOM Edge Plus with software syngo CT VB10A .	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=14498	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
# Various Systems Using Remote Desktop Services for Microsoft Windows Operating Systems	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited		
Vereos PET/CT	Philips Healthcare	hilips Healthcare Saudi Arabia Ltd	/Secure/CA/CaViewRecal	

Electro mechanical medical devices


CLEO Patient Monitor /Tranquility VS Patient Monitor	Infinium Medical, Inc.	Saudi Health Services Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
da Vinci Xi EndoWrist SureForm 60 Reload	Intuitive Surgical Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14	
Day Set III HP	Bracco Injeneering S.A..	N/A	/Secure/CA/CaViewRecal	
# EVOTECH Endoscope Cleaner and Reprocessor Systems	Advanced Sterilization Products Division of Ethicon,Inc. A Johnson & Johnson	Johnson & Johnson Medical Saudi Arabia Limited		
# MiniMed™ Paradigm™ Series and MiniMed™ 508 Insulin Pumps ,	Medtronic SA	Medtronic Saudi Arabia		
Powerheart G5 Automatic AED	Cardiac Science Corporation	Mohammed Binmahfouz Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
Prismaflex devices with software version 8.10 .	Baxter Healthcare	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
Quantum Perfusion Systems ,	Spectrum Medical Ltd.	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
REVACLEAR 400, REVACLEAR 300 Dialyzer	Baxter Corp Canada	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
Solar Blue	al Measurement Syster	Gulf Medical Co.	/Secure/CA/CaViewRecal	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Support.set Säuglinge, hilite 800 LT, rheoparin beschichtet, Modell Medos	Xenios AG	Al Mofadaly Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14521	
TechnegasPlus Generator	Cyclomedica Australia Pty Ltd	Intl Radiation Technology - IRT	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
Warming Solution Set 205, Warming Kit 102, Vitrification Solution Set 110, Vitrification Kit 101	REPROLIFE	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	

Healthcare facility products and adaptations

Getinge Sterilizer	Getinge Disinfection AB	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
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In vitro diagnostic devices

AQUIOS IMMUNO-TROL Low Cells	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
ColoCARE	elena Biosciences Europe	Fuad Abdul Jalil Al Fadhli & Sons	/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
Combur-Test UX, Chemstrip 10 A, Urisys 1100	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
Creatine Kinase on the Atellica Chemistry platform.	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14523	
Dimension Vista System, Cyclosporine (CSA) Assay	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14523	
# Vacutainer Fluoride Tubes for Blood Alcohol Determinations	BD Biosciences	Becton Dickinson B.V.		
Yumizen H1500 and H2500	HORIBA ABX SAS.	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	

Non-active implantable devices

LEGION Optima Cutting Block.	Smith & Nephew inc	Smith & Nephew inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=14523	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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MAGEC System , e Specialized Orthopae		Amin Medical Instruments Co. Lt	Secure/CA/CaViewRecall	
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Ophthalmic and optical devices


Disposable 25GA Vitrectomy Cutter ,	johnson & johnson Surgical Vision Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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Nucleus Hydrodissector [Sauter] Cannula 40x22mm(27Gx7/8in)	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14504	
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Single-use devices

IntraClude Intra-Aortic Occlusion Devices ,	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCC)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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# Luer Lock Sets	Molded Products Inc	N/A		
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# Monarch Aspirating Biopsy Needles	Auris Health Inc	N/A		
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Regimen 28 Day Glutaraldehyde Sterilizing and Disinfecting Solution	Metrex Research, LLC	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14527	
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Stainless Steel Interstitial Needles, 17 Gauge ,	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=1	
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