



SBED Weekly Update 03-Jul-17

Dear,
SBED team is pleased to inform you that **28** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 6/26/2017 to 7/1/2017
In order to view more details, click the links and for ECRI alerts see the attachments

NOTE:

FSCA / Recalls are classified into three categories, representing the potential risk to public health: Class I : High Risk, Class II : Medium Risk and Class III: Low Risk.
FSN (Field Safety Notice) : A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Active Implantable Devices




#	New	Implantable Pulse Generators Used with Neuromodulation Systems	7/1/2017	Thoratec Corp	Arabian Trade House Est.	2	Link
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Diagnostic and therapeutic radiation devices

New	Artis, X-Workplace, Sensis and ARCADIS Systems	6/27/2017	SIEMENS	Siemens Medical Solutions	FSN	https
New	HITACHI ARIETTA Prologue.	6/29/2017	Hitachi Medical Corp	ABDULREHMAN AL GOSAIBI GTB	FSN	https
New	iGUIDE® Software 2.2	6/27/2017	Elekta Limited	Medical Regulations Gate	FSN	A/Ca\
New	JiveX ,	6/27/2017	is Technology Transfer Gn	N/A	FSN	A/Ca\

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Nicolet Elite Probe	6/29/2017	Natus Neurology	Applies & Services Co.Ltd	FSN	A/Cal
New	SPECT E.CAM, SPECT Symbia, SPECT MI, PET Biograph, PET Horion, PET Advanced Workflow	6/27/2017	SIEMENS	Siemens Medical Solutions	FSN	https://ncmdr
New	syngo Imaging, syngo.plaza, syngo Dynamics, syngo Imaging XS, MagicLink A, syngo Workflow MLR, syngo Workflow SLR , syngo.via , and syngo.via ProtoNeo	6/27/2017	SIEMENS	Siemens Medical Solutions	FSN	https://ncmdr.sfd.gov.sa/Se

Electro mechanical medical devices

#	New	Hemofiltration Standard Packs Including BC 60 Plus-T 8036 Tubing Sets	7/1/2017	MAQUET Inc	Gulf Medical Co.	2	
	New	HL7-WorklistServer/Commander	6/26/2017	Getemed Medizin	GE Healthcare	FSN	https://nc
#	New	Maquet/Datascope CS Intra-Aortic Balloon Pumps	6/30/2017	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	1	
#	New	PhotonBlade Electrosurgical Devices	7/1/2017	Invuity, Inc	N/A	2	
	New	PrisMax Hemodialysis Machine	6/29/2017	Baxter Healthcare	Baxter AG	FSN	https

In vitro diagnostic devices

	New	FLACON POUR ULTRA-TURRAX AVEC BILLES ET EAU BIO MOL STERILE	6/29/2017	CENTRE EUROPEEN DE BIOTECHNOLOGIE (CEB) SA	N/A	FSN	https://nc
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Non-active implantable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	3DKnee System	6/27/2017	Encore Medical, Lp	Al Ewan Medical Compan	FSN	A/Cal
New	Comprehensive Nano Humeral Component PPS.	6/27/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	https
New	Trauma, Guide Wires 70cm	6/26/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https




Ophthalmic and optical devices

New	Vitrectomy TDC Kit. (23 gauge / 0.6 mm)	6/26/2017	D.O.R.C. Dutch Ophthalmic Research	First Gulf Co.	FSN	https
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Reusable devices

New	RM Classic flexible reaming shafts/countersink reamers new generation	6/27/2017	Mathys Ltd Bettlach	Isam Economic Co.	FSN	https://nc.mdr.sfda
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Single-use devices

New	SONIC MICROCATHETER ,	6/27/2017	Balt Extrusion.	Ikar Establishment	FSN	https	
#	New	22 G × 1 ½-Inch SafetyGlide Needles Contained in Kits	7/1/2017	BD Biosciences	Becton Dickinson B.V.	2	
#	New	3D Revascularization Devices	6/30/2017	Penumbra, Inc.	Thimar Al Jazirah Healthcare Co.	1	
New	I.V. Administration Sets with NanoClave® manifold	6/27/2017	ICU Medical, Inc	AL-KAMAL Import	FSN	https://nc	
#	New	mcompass Balloon 2-Channel Catheters	7/1/2017	Medspira LLC	N/A	2	
New	NeuroSpeed PTA Balloon Catheter	6/29/2017	Acandis GmbH & Co. KG	N/A	FSN	https	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	PROLENE Polypropyl. Suture; NUROLON Nylon Suture	6/26/2017	Ethicon Inc A Johnson & Johnson Co	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc
# Update	Unna Z Unna Boot Bandages with Zinc and Calamine	7/1/2017	Medline Industries Inc....	Ikar Establishment	2	
# New	Various Tissu-Trans Products	6/30/2017	Shippert Medical Technologies Inc	N/A	2	

* The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI

*  indicates that medical devices subject to removal and/ or destroyed action.

* SBED Team Recommend ensuring The listed Distributors in this report as they may differ from the distributors you are dealing with

SBED is devoted to receive the adverse event report and feedback information about any medical devices malfunction from hospitals and healthcare facilities all around KSA, studying them and collaborative working with manufacturers, authorized representatives and distributors to take the right action and assuring the proper safe performance.

To see recent recalls kindly visit the following link:

<http://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx>

In case you find an effected medical devices by any of the published FSN/Recalls, we urges you to contact the local representative and the National Center for Medical Device Reporting in order to ensure corrective or planed action been implemented.