



SBED Weekly Update

06-Mar-18

Dear,

SBED team is pleased to inform you that **42** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 2/26/2018 to 3/4/2018
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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Anaesthetic and respiratory devices

#	New	ETCO2 OxyMask Oxygen Masks ,	3/4/2018	Southmedic Inc	Healthcare Systems Trading Est.	2	Attac hed
	New	Fabius GS Premium, Tiro, Tiro D-M, MRI, plus, plus XL ,	2/26/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	https://nc.mdr
	New	Gas bottle holder for helicopter HKH 8880	3/4/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	https://nc
	New	HAMILTON-C1/ -C2/ -C3/ -C6 Ventilator unit	2/27/2018	Hamilton Medical Inc	Taleiamedical	FSN	https://nc

Assistive products for persons with disability

	New	Futuro Quick Strap Ankle Support	3/1/2018	3M Health Care Ltd	3M company	2	https://nc
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Dental devices

New	Dentin/Enamel Etch	3/1/2018	Cosmedent, Inc.	N/A	2	A/Ca\
New	Legacy1 SBM Implant	2/27/2018	Direct Sybron Manufactur	Abdullah Alzoman Est. for	FSN	A/Ca\
New	Max Implant System	3/1/2018	Keystone Dental Inc.	N/A	2	A/Ca\
New	RESTORE, STAGE1, RENOVA PRIMASOLO AND PRIMACONNEX DENTAL IMPLANTS	3/1/2018	Keystone Dental Inc.	N/A	2	https://nc.mdr.sfda

Diagnostic and therapeutic radiation devices

New	Artis Q and Q.Zen, Artis Zee and Zeego, Axiom Artis	2/26/2018	Siemens Medical Solutions	Siemens Medical Solutions	2	https://nc.mdr
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New	Centricity PACS-IW ,	2/28/2018	GE Healthcare	GE Healthcare	FSN	A/Ca\
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#	New	INFINIX VC-I Interventional Angiography Systems	3/4/2018	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	Attac hed 
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New	Ingenuity Flex, Ingenuity CT, Ingenuity Core, Ingenuity Core128, Brilliance iCT, Brilliance iCT SP, Brilliance Big Bore Oncology, Brilliance Big Bore Radiology, Brilliance 16, Brilliance 40, Brilliance 64, IQon, Brilliance 6, Brilliance 10	2/27/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRec
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New	Protura Software which utilizes Elektas iCOM interface	2/26/2018	Med Tec Inc	Medical regulations gate	2	https://nc.mdr
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New	Radrex-i (Canon)	2/27/2018	Canon Inc	N/A	FSN	A/Ca\
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New	VeriQ System	3/1/2018	Medistim ASA	Gulf Medical Co.	2	A/CaV
# New	VP-7000 Video Processor Systems	2/26/2018	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	2	Attache

Electro mechanical medical devices

New	ARROW PICC	2/26/2018	Arrow International Inc	Gulf Medical Co.	2	A/CaV
# New	Car Pole Carts ,	2/26/2018	Micromed SpA	N/A	2	ttache
New	Cook Aspiration Unit ,	3/1/2018	Cook Medical	NAFA Medical	2	A/CaV
New	FMS Gravity Tube Set	2/26/2018	DePuy Ireland UC	Johnson Medical Saudi Ar	2	A/CaV
New	HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs ,	2/26/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc.mdr.
# New	J-Plasma Handpieces ,	2/27/2018	Sovie Medical Corporation	Bio Standards	2	ttache
New	LUCAS 2 Chest Compression System ,	3/1/2018	Jolife AB.	Al-Jeel Medical & Trading Co. LTD	1	https://nc
New	Natus NicoletOne 32Ch Ambulatory EEG Record System	3/1/2018	Natus Neurology	Medical supplies & Services Co.Ltd Mediserv	2	https://nc.mdr.

In vitro diagnostic devices

New	Alinity hq Analyzer ,	2/27/2018	Abbott	pplies & Services Co.Ltd	FSN	A/CaV
New	AQUIRE system ,	3/4/2018	Radiometer America Inc	Salehiya Trading Est.	FSN	A/CaV
New	Cobas b221	2/27/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	A/CaV
# New	HyClone RPMI-1640 Cell Culture Media	2/26/2018	GE Healthcare	GE Healthcare	FSN	Attache

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	LIFECODES Typing Kits	3/4/2018	Immucor GmbH.	Applies & Services Co.Ltd	FSN	A/Ca


Non-active implantable devices

New	NexGen LPS	2/26/2018	Zimmer Inc.....	Isam Economic Co.	2	A/Ca
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Reusable devices


New	AVID TruCustom	3/4/2018	Avid Medical, Inc.	N/A	2	A/Ca
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Single-use devices

#	New	Closed Suction Kits with Flex Connectors ,	2/27/2018	Halyard Health, Inc..	MEDICARE DRUG STORE COMPANY	2	Attac hed	
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New	Destination Guiding Sheath	3/1/2018	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	https://nc
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#	New	Dialysate Sacks ,	2/26/2018	NxStage Medical, Inc.	DWAN MEDICAL SERVIC	2	ttache	
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#	New	MindFrame Capture LP Devices	3/4/2018	Medtronic SA	Medtronic Saudi Arabia	1	Attac hed	
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New	Pericardiocentesis Kits ,	3/4/2018	Merit Medical Systems, Inc.	cal Technology Establishr	FSN	A/Ca
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New	ProLite Mesh	2/26/2018	rium Medical Corporation	Saudi Sicli Company	2	A/Ca
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#	New	PVP Scrub Solution ,	2/27/2018	Medline Industries Inc....	Ikar Establishment	2	ttache	
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New	Sterile IV Start Kit	3/4/2018	B Braun Medical Inc	Applies & Services Co.Ltd	2	A/Ca
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New	Sterilization Wrap	3/1/2018	STERIS Corporation..	el Medical & Trading Co.	2	A/Ca
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New	U-100 Insulin Syringe 0.5mL 27G and 29G	3/1/2018	Tae-Chang Industrial Co.	ILIA TRADING(ANNASBAN	2	https://nc
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- * 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.