



SBED Weekly Update 24-Jul-17

Dear,
SBED team is pleased to inform you that **41** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/17/2017 to 7/23/2017
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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Anaesthetic and respiratory devices

#	New	731 Ventilators	7/17/2017	ZOLL Medical Corp	Hammad Medical Servic	2	
	New	Timer, General Laboratory	7/17/2017	wo Medical Technologies,	N/A	2	A/Cal
#	New	Various Astral Ventilators, External Batteries, and Battery Packs	7/18/2017	Resmed Limited	cigalah group	2	

Assistive products for persons with disability

#	New	Freeway Easy Fit Systems with Swiveling Trolley	7/18/2017	Prism Medical Ltd	N/A	2	
#	New	Heron Toilet and Bath Chairs	7/17/2017	R82	N/A	2	

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Prevalon AirTAP Booster Pumps	7/17/2017	Sage Products LLC	Teriag International	2	
	New	SANO Liftkar PT electric stairclimber	7/20/2017	SANO GmbH	N/A	FSN	https://nc

Diagnostic and therapeutic radiation devices

	Update	Accu-Chek Connect diabetes management app.	7/20/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc
	New	Elite 2,Elite 3,Elite 5	7/17/2017	Natus Neurology	Supplies & Services Co.Ltd	2	A/CaV
	Update	Lantis Commander oder Lantis	7/20/2017	SIEMENS	Siemens Medical Solutions	FSN	https://nc

Electro mechanical medical devices

#	New	3T Heater-Cooler Systems	7/17/2017	LivaNova PLC	cigalah group	2	
	New	Conductivity/TDS Calibrator Solution.	7/23/2017	Mesa Laboratories, Inc.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https://nc
	New	Euphora and Solarice Angioplasty catheter, balloon dilatation	7/17/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
#	New	HomeChoice and HomeChoice PRO Automated PD Cyclers	7/17/2017	Baxter Corp Canada	Baxter AG	2	
	New	NovoPen Echo	7/19/2017	Novo Nordisk	Novo Nordisk	2	A/CaV
	New	Pentax Video Duodenoscope	7/17/2017	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd	2	https://nc
#	New	Spinous Process Clamps Used with StealthStation Systems	7/17/2017	Medtronic Navigation Inc	Al Amin Medical Instruments Co. Ltd.	2	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Stopcock, i.V. Set	7/17/2017	ICU Medical, Inc	AL-KAMAL Import	2	A/CaV

Hospital hardware

New	Sekusept, Incidin, Incidur	7/20/2017	Ecolab Deutschland GmbH	Salehiya Trading Est.	FSN	A/CaV
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In vitro diagnostic devices

New	Alere HIV Combo	7/19/2017	Alere LTD	Applies & Services Co.Ltd	2	A/CaV
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New	Analyzer (software) for FluoroType HSV VER 1.0	7/20/2017	Hain Lifescience GmbH	Bio Alternatives Establishment	FSN	https
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#	New	APTT Si L Minus Assays	7/18/2017	Helena Laboratories	Arabian Trade House Est.	2	A/CaV
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New	B·R·A·H·M·S anti-Tgn RIA	7/20/2017	Thermo Fisher...	-MOHANAD MEDICAL E	FSN	A/CaV
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New	cobas c 501 module cobas c 502 module	7/17/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
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New	Dimension Clinical Chemistry System and Dimension Vista System	7/19/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://nc
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New	Elecsys Digoxin, cobas e 801 module	7/20/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
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New	GenoType SugarTol VER 1.0	7/20/2017	Hain Lifescience GmbH	Bio Alternatives Establishment	FSN	https
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#	New	INNOVANCE Direct Thrombin Inhibitor Assays Used with Sysmex CS-5100 Systems	7/18/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	2	A/CaV
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New	MicroTrak Chlamydia trachomatis Direct Specimen	7/20/2017	Trinity Biotech plc.	AL OSOOL MEDICAL TRADING COMPANY	FSN	https://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Synchron Systems Salicylate Reagent	7/19/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	https
New	Unyvero P55 Pneumonia Cartridge Set	7/20/2017	Curetis GmbH	N/A	FSN	https

Laboratory equipment


New	ID-Papain.	7/17/2017	io-Rad Medical Diagnostik	ULREHMAN AL GOSAIBI	FSN	A/Ca
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Non-active implantable devices

New	DRILL BIT MINI-QUICK CONNECT	7/20/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	https
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Ophthalmic and optical devices


New	Colonovideoscopes CF-Y0067-L	7/20/2017	Olympus	Salehiya Trading Est.	FSN	https
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#	New	Sample Collectors Contained in InflammaDry Kits	7/17/2017	Quidel Corporation	ABDULLA FOUAD HOLDING COMPANY	2	
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Reusable devices

New	Nitinol RF Reusable Electrodes	7/19/2017	Cosman Medical	N/A	1	https
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Single-use devices

#	New	0.9% Sodium Chloride Injections and 5% Dextrose Injections in 100 mL VIAFLEX Plastic Containers	7/17/2017	Baxter Corp Canada	Baxter AG	2	
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#	New	0.9% Sodium Chloride Injections in 250 mL VIAFLEX Plastic Containers	7/17/2017	Baxter Corp Canada	Baxter AG	2	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Aequalis Ascend Flex Shoulder System PTC Humeral Stems	7/19/2017	Tornier Inc	N/A	2	https://nc
# New	Dukal Burn Sheets	7/17/2017	DUKAL	N/A	2	https://nc
New	Mako Internal cPCI Card Cage	7/19/2017	MAKO Surgical Corp	N/A	2	https

* 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.