



SBED Weekly Update 31-Jul-17

Dear,
SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/24/2017 to 7/27/2017
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	Astral 100, Astral 150	7/25/2017	Resmed Limited	cigalah group	FSN	A/Cal
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Assistive products for persons with disability

New	Flex grab rail adhesive mount	7/24/2017	Etac	Medicare Center	FSN	https://nc
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#	New	Model M320 Anti-Gravity Treadmills ,	7/27/2017	AlterG Inc.	N/A	2	
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New	OXFORD DIPPER	7/25/2017	Joerns Healthcare Limited	el Medical & Trading Co.	FSN	A/Cal
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#	New	ReoAmbulator Systems	7/25/2017	Motorika Medical	N/A	2	
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New	Voyager Evo rigid frame wheelchair	7/24/2017	Otto Bock Healthcare Products GmbH	Al Gaim Comm. Est.	FSN	https://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Diagnostic and therapeutic radiation devices

	New	Airo Mobile CT scanner	7/24/2017	BrainLAB	el Medical & Trading Co.	FSN	A/Ca\
	New	OEC 9800 and OEC 9900 Elite	7/24/2017	GE Medical Systems	GE Healthcare	2	https://nc
#	Update	Philips M1783A and M5526A Sync Cables	7/27/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	

Electro mechanical medical devices

#	New	Maquet/Datascope CS Intra-Aortic Balloon Pumps ,.	7/24/2017	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	2	
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In vitro diagnostic devices

	New	ACCURUN 51 Multi-Marker Hepatits Positive Control	7/25/2017	SeraCare Life Sciences	N/A	FSN	https://nc mdr.
	New	Creatinine PAP FS	7/24/2017	ys Diagnostic Systems Gr	Ghuyum Scientific Tradir	FSN	A/Ca\
	New	FastPack IP Vitamin D-Immunoassay	7/24/2017	Qualigen Inc.	Bio Standards	FSN	https://nc
	New	IPertussis Toxin gG Quantifizierungs-Set	7/24/2017	VIROTECH Diagnostics GmbH	N/A	FSN	https://nc
	New	Liquid Urine Control Level 3	7/26/2017	Randox Laboratories Ltd.	Bio Standards	FSN	https://nc
	New	Ortho BioVue System Rh/K Cassette	7/25/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https://nc
	New	Pacific Hemostasis Fibrinogen Degradation Products	7/27/2017	Fisher Diagnostics	Farabi Trading Establishment	2	https://nc mdr.

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Phadia 1000, all Instrument Software (ISW) versions	7/24/2017	ThermoFisher.	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr
New	Syva EMIT 2000 Tacrolimus und Sirolimus	7/24/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	https://nc
New	ThermoScientific Oxoid GC Agar	7/25/2017	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	FSN	https://nc
New	Total IgE-HRP EIA	7/24/2017	e-Achterrath Laboratorier	Medical and Hospital Sup	FSN	A/Cal

Non-active implantable devices


New	Persona Partial Knee Guide Size 8	7/24/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https://nc
New	Vivexx Carotid Stent	7/24/2017	d GmbH & Co. Medizintec	C.R. BARD Saudi Arabia	FSN	A/Cal

Reusable devices

#	New	ReNew Reusable Grasper and Dissector Tips	7/24/2017	Microline Surgical Inc	Dawha Medical	2	
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Single-use devices

	New	CADD BlueStriped Administration Set	7/26/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	https://nc
	New	Converters(R) Tiburon(R) Arthroscopy Drape	7/26/2017	Cardinal Health..	Medical Technology Establishment	2	https://nc
#	New	ENTRAL ENFit Nasogastric Feeding Tubes	7/27/2017	Maxter Catheters	Reem Alwasat for Trading Company.	2	
#	New	SPY-PHI Drapes	7/25/2017	lovadaq Technologies Inc	Arabian Trade House Est.	2	

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Vistec X-Ray Detectable Sponges	7/24/2017	Medtronic SA	Medtronic Saudi Arabia	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.