



SBED Weekly Update 17-Jul-17

Dear,
SBED team is pleased to inform you that **36** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/10/2017 to 7/13/2017
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	Distributor	Class	Link
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Anaesthetic and respiratory devices

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
	New	CO2 Connectors Used with DIN O2 Terminal Units	7/11/2017	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	2	Attached
	New	Olympic Pasteurmatic 3000; Olympic Pasteurmatic 3500	7/11/2017	Natus Medical Inc.	Saudi Health Services Co. Ltd.	2	https://nc
	New	WATO EX-65, WATO EX-55, A5 and A7 anesthesia machines	7/13/2017	Shenzhen Mindray	Salehiya Trading Est.	FSN	https://nc

Diagnostic and therapeutic radiation devices



	Update	Artis, X-Workplace, Sensis and ARCADIS Systems	7/13/2017	SIEMENS	Siemens Medical Solutions	FSN	https
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
New	EVIS EXERA DUODENOVideoscope TJF-145	7/11/2017	Olympus	Salehiya Trading Est.	FSN	https://nc	
New	Lantis Commander oder Lantis	7/11/2017	SIEMENS	Siemens Medical Solutions	FSN	https	
New	Model 105AspireHC and Model 106 AspireSR VNS Therapy Generators	7/10/2017	LivaNova PLC	cigalah group	FSN	https://nc	
New	Philips Brilliance iCT	7/12/2017	Philips Healthcare	s Healthcare Saudi Arabi	FSN	A/Ca	
New	ProteusPlus, Proteus 235, Proton Therapy System	7/11/2017	Ion Beam Applications S.A.	N/A	2	https	
#	New	Radsuite Software	7/11/2017	Merge Healthcare Corp.	N/A	2	ttache 
#	New	Schiller PB 1000 Used with Hemo Software	7/11/2017	Merge Healthcare Corp.	N/A	2	Attac 
New	SoKINOX / SERVINO	7/12/2017	aqueet Cardiopulmonary A	I-Faisaliah Medical System	FSN	A/Ca	
New	syngo Workflow MLR.	7/11/2017	SIEMENS	iemens Medical Solution	FSN	A/Ca	

Electro mechanical medical devices

New	Arrow Glide Thru PeelAway Sheath/Dilator Introducer	7/11/2017	Arrow International Inc	Gulf Medical Co.	2	https://nc
New	Stryker System G handpieces	7/12/2017	Stryker Instruments	Al-Faisaliah Medical System	FSN	https
New	Tenaxis Medical ArterX(TM) Surgical Sealant	7/11/2017	Mallinckrodt AG	Dar Al-Zahrawi Medical Co. LLC	2	https://nc

In vitro diagnostic devices





Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
Update	Calibrator 30 (2 pack) used with ADVIA Centaur Enhanced Estradiol (eE2) on the ADVIA Centaur, Centaur XP and Centaur XPT systems	7/10/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://ncmdr.sfda.gov.s
New	cobas e 411 and Elecsys 2010 analyzer	7/10/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
New	cobas e 601, cobas e 602 MODULAR Analytics	7/10/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
New	CTAD-Monovette	7/10/2017	Sarstedt AG & Co.	LA FOUAD HOLDING CO	FSN	A/Ca
# New	DI-60 Cell Image Analyzers	7/11/2017	CellaVision AB	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac 
New	QIAamp DSP Virus Kit	7/10/2017	QIAGEN Ltd	LA FOUAD HOLDING CO	FSN	A/Ca
New	Stat Profile Prime	7/12/2017	ova Biomedical Corporatio	DWAN MEDICAL SERVIC	FSN	A/Ca
# New	Tomcat Instruments	7/11/2017	Hologic Inc	pplies & Services Co.Ltd	2	ttache 
New	Yumizen H500 CT	7/12/2017	HORIBA ABX SAS.	Photographic Supplies C	FSN	A/Ca

Non-active implantable devices

New	LE-Cage	7/13/2017	OHST Medizintechnik AG	N/A	FSN	A/Ca
New	POWER DRILL TORQUE LIMITER	7/11/2017	Orthofix	Arabian Health Care Supply Co. (AHCSC)	FSN	https
New	Tibial Augment Screw	7/11/2017	Exactech	N/A	2	A/Ca

Single-use devices

# New	11 G Elcam Medical VersaSafe Plastic Cannulae	7/11/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	Attac 
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New	AAA Wire WiTRAC	7/11/2017	flex Feinwerktechnik Gmk	Mais Co. For Medical Pro	FSN	A/Ca	
#	New	Arrow Pressure-Injectable PICC Kits	7/11/2017	Arrow International Inc	Gulf Medical Co.	2	Attac 
New	Asahi APS-H Series Hemodiafilter	7/13/2017	Asahi Kasei Medical Co., Ltd.	Medical Care Alliance Establishment	FSN	https	
#	New	Medsurg Connection - Various Sterile Conventional Syringes and Needles	7/11/2017	Cardinal Health..	Medical Technology Establishment	2	Attac hed 
#	New	Over-Pressure Safety Valves	7/11/2017	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	Attac 
New	Percutaneous Introducer Sheath	7/12/2017	OptiMed Medizinische Instrumente GmbH	Syts Trading Est.	FSN	https	
#	New	STAT 2 IV Gravity Flow Controllers and Extension Sets	7/11/2017	ConMed Corporation	Saudi Import Co. Banaja	2	Attac hed 

* 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.