



SBED Weekly Update 16-Sep-15

Dear,

SBED team is pleased to inform you that **37** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 9/8/2015 to 9/13/2015
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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Assistive products for persons with disability

New	Charder Weigh Scale	9/8/2015	Charder electronic	N/A	FSN	A/Cal
New	Pixi Sulki Stroller	9/13/2015	Eurovema AB	N/A	FSN	A/Cal
New	silicon tube 1008	9/8/2015	Hippokratec GmbH	N/A	FSN	A/Cal

Diagnostic and therapeutic radiation devices

New	Allura Xper FD	9/8/2015	Philips Healthcare	s Healthcare Saudi Arabi	FSN	A/Cal
New	Hitachi MRI Systems AIRIS Vento, AIRIS Vento LT, APERTO Eterna, APERTO Lucent, Echelon and Oasis	9/8/2015	Hitachi Medical Corp	ABDULREHMAN AL GOSAIBI GTB	FSN	http://nc.mdr.sfda

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Syngo.plaza;picture archiving and communications system	9/10/2015	SIEMENS	Siemens Medical Solutions	2	http://nc

Electro mechanical medical devices

New	CryoConsole Models	9/8/2015	Medtronic..	I-Faisaliah Medical System	2	A/Ca
New	DPM 7 Monitor	9/10/2015	Shenzhen Mindray	Salehiya Trading Est.	2	A/Ca
New	Neptune® 2 Docker (STRYKER NEPTUNE® 2 WASTE MANAGEMENT SYSTEM)	9/8/2015	Stryker Communications	Al-Faisaliah Medical System	FSN	http://nc.mdr
New	OFP-2 Flushing Pump Accessory- MAJ-1606 Instrument Channel	9/13/2015	Olympus	Salehiya Trading Est.	FSN	http://nc
New	RUSSKA Rollator Standard and Rollator Aluminium	9/8/2015	Ludwig Bertram GmbH	N/A	FSN	http://nc
New	Temporary cardiac pacing wire	9/13/2015	Ethicon Endo Surgery Inc	ABDULREHMAN AL GOSAIBI GTB	FSN	http://nc
New	Vinci Xi Surgical System	9/8/2015	Intuitive Surgical Inc	Gulf Medical Co.	1	A/Ca
New	Zethon, Sterile Bipolar Forceps	9/8/2015	Synergy Health	N/A	FSN	http://nc

In vitro diagnostic devices

New	ADVIA Centaur Systems HBsAg II	9/8/2015	Siemens Medical Solutions	Siemens Medical Solutions	FSN	http://nc
New	ADVIA Chemistry XPT system..	9/13/2015	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	http://nc
New	BD Affirm VPIII Microbial Identification Tests	9/8/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	http://nc

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New	cobas® Liat Analyzer	9/10/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	2	A/CA
New	iChem Velocity Urine Chemistry Strips.	9/8/2015	IRIS Diagnostics	Arabian Medical Marketing Co. (AMCO)	2	http:
Update	LABType HD DRB1 Typing Test	9/8/2015	One Lambda Inc	Farabi Trading Establishment	FSN	http:
New	syngo lab data manager.	9/8/2015	hs Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/CA
New	Various Remel Mueller-Hinton Broth	9/13/2015	Thermo Fisher...	AL-MOHANAD MEDICAL EST	FSN	http:

Laboratory equipment

New	Spectra Optia Apheresis System.	9/8/2015	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	1	http:
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Non-active implantable devices

Update	Actifuse ABX and Actifuse MIS System	9/8/2015	Baxter Healthcare	Baxter AG	1	http:
New	ALIQUOT Delivery System Complete Set	9/8/2015	Stryker Communications	Al-Faisaliah Medical System	2	http:
Update	ALIQUOT Delivery System Complete Set	9/13/2015	Stryker Communications	Al-Faisaliah Medical System	2	http:
New	Coloplast urogynaecological surgical mesh, Aris Kit, Altis System	9/8/2015	Coloplast A/S	Al Hammad Medical Services	1	http://nc.mdr.
New	CrossCHECK™	9/10/2015	ght Medical Technology,	Saudi Import Co. Banaja	2	A/CA
New	GYNEMESH PS & TVT Devices	9/8/2015	Ethicon Inc	Teriag International	1	http:
New	JenaValve prosthesis	9/8/2015	naValve Technology Gmb	N/A	FSN	A/CA

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	METHA Titanium Cone Adapter (Neck)	9/8/2015	Aesculap	Gulf Medical Co.	FSN	http:
New	Trial Adaptor Head	9/10/2015	Limacorporate	N/A	2	A/Cal

Ophthalmic and optical devices

New	Emergency Sterile Eye Wash	9/8/2015	Amanta Healthcare	N/A	FSN	http:
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Single-use devices

New	Covidien Monoject 0.9% Saline Flush Syringes and Prefill Double Pouches	9/10/2015	Covidien LLC	Covidien AG	2	http://nc
New	Kimvent closed suction system	9/13/2015	Halyard Health Co.	N/A	2	http:
New	Magic3 Intermittent Catheter with Sure Grip Hydrophilic Coated Silicone Coude tip	9/10/2015	C.R. Bard, Inc.	Arabian Trade House Est.	2	http://nc mdr.
New	MEDTRONIC PERFUSION TUBING PACKS and MEDIVATORS HEMOCOR	9/10/2015	Medtronic Advanced Energy, LLC	Gulf Medical Co.	2	http://nc

* 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.sfd.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.