



SBED Weekly Update 09-Sep-15

Dear,
SBED team is pleased to inform you that **34** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 9/1/2015 to 9/6/2015
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
-----------	---------------	-----------	--------------	------------	-------	------

Assistive products for persons with disability

New	Zippie IRIS and Quickie IRIS Wheelchairs	9/3/2015	Sunrise Medical	Al-Enayah Company	2	http:
-----	--	----------	-----------------	-------------------	---	-----------------------

Diagnostic and therapeutic radiation devices

New	ACUSON SC2000 ultrasound systems.	9/3/2015	Siemens Medical Solutions	Siemens Medical Solutions	FSN	http:
New	Allura Xper Systems..	9/3/2015	Philips Healthcare	s Healthcare Saudi Arabi	FSN	A/Cal
New	disposable reflective marker spheres.	9/1/2015	BrainLAB	Al-Jeel Medical & Trading Co. LTD	FSN	http:
New	Edwards Pressure Monitoring Kit & Set	9/3/2015	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	http:

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	GE Healthcare 3.0T MR systems: Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA PET/MR 3.0T, SIGNA HDxt 3.0T, SIGNA HDx 3.0T, SIGNA HD 3.0T, SIGNA Excite 3.0T, SIGNA 3.0T	9/1/2015	GE Healthcare	GE Healthcare	FSN	http://ncmdr.sfda.gov.sa/Secure/

Electro mechanical medical devices

New	Accu-Chek Insight	9/3/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	FSN	A/Cal
New	Alaris Syringe Pumps.	9/3/2015	CareFusion 206 Inc,	Saudi Import Co. Banaja	FSN	A/Cal
Update	Easypump II Elastomeric Infusion Pumps	9/3/2015	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	http:
Update	Edwards Commander Delivery System	9/3/2015	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	FSN	http:
Update	LIFEPAK 1000 Defibrillators	9/3/2015	Physio Control Inc	Al-Jeel Medical & Trading Co. LTD	2	http:
New	Medicina enteral syringe pumps	9/1/2015	Medicina	Al Hammad Medical Services	FSN	http:
New	Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Pre-connect	9/3/2015	Covidien LLC	Covidien AG	1	http://ncmdr.
New	Reprocessed Ethicon Excel Trocar Sleeve	9/3/2015	Stryker Endoscopy	Al-Faisaliah Medical System	2	http:

In vitro diagnostic devices

New	ABL90Flex battery module used with Radiometer ABL90FLEX blood gas analyser (Optional battery)	9/3/2015	Radiometer America Inc	Salehiya Trading Est.	2	http://ncmdr.sfda.
-----	---	----------	------------------------	-----------------------	---	------------------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	ASO	9/3/2015	DIALAB GmbH	Abdullah A. Baghaffar	1	A/Cal
New	chromID S. aureus range products	9/3/2015	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	http:
New	CONTOUR NEXT control solutions	9/3/2015	Bayer Healthcare LLC	Abdulrauf Ibrahim Batterjee & Bros.	1	http:
Update	Elecsys CMV IgM assay (04784618190) - Diluent Universal.	9/3/2015	Roche Diagnostics Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	http://nc
New	G6PD Screening Controls	9/3/2015	Pointe Scientific Inc	N/A	2	A/Cal
New	HardyCHROM MRSA	9/3/2015	Hardy Diagnostics	N/A	2	A/Cal
New	Mueller Hinton 2 Agar	9/3/2015	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Cal

Non-active implantable devices

New	7, 9, & 11Hole VL Gridlock Fibula Plating System	9/6/2015	Trilliant Surgical Ltd	N/A	2	http://nc
New	Actifuse ABX and Actifuse MIS System	9/3/2015	Baxter Healthcare	Baxter AG	1	http:
New	Cannulated Headless Compression Screw, Length 22 m	9/3/2015	Synthes USA (HQ) Inc.	Isam Economic Co.	FSN	http://nc
New	Salto Talaris Tibial Guide	9/3/2015	Tornier Inc	N/A	2	A/Cal
New	Synthes Application Instrument for Sternal ZIPFIX	9/3/2015	Synthes Inc	Isam Economic Co.	2	http://nc
New	Tiger Cannulated Tray Lid	9/3/2015	Trilliant Surgical Ltd	N/A	2	A/Cal

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Vision RingLoc Acetabular System	9/3/2015	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	http://nc

Ophthalmic and optical devices

New	OPD-Scan III Refractive Power/Corneal Analyzer Ophthalmic	9/3/2015	Nidek Co. Ltd.	Al Amin Medical Instruments Co. Ltd.	2	http://nc
-----	---	----------	----------------	--------------------------------------	---	-----------------------------------

Reusable devices

New	Disposable paper filter for sterilization containers	9/3/2015	Stryker Leibinger GmbH & Co.KG	Zimmo Trading Establishment.	FSN	http://nc
-----	--	----------	--------------------------------	------------------------------	-----	-----------------------------------

Single-use devices

New	FLEXixBFSLIP ENDOTRACHEAL TUBE STYLET WITH SOFT DISTAL TIPFLEXISLIP STYLET, STERILE PACK	9/3/2015	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	http://nc http://nc.mdr.sfd http://nc.sfd
-----	--	----------	------------------	-------------------------------------	-----	---

New	GLOSAIR™ 400 Cartridge	9/1/2015	Advanced Sterilization Products	MAAMOUN TAMER & Co	2	http://nc
-----	------------------------	----------	---------------------------------	--------------------	---	-----------------------------------

New	PICC Kits and VPS Access Kits with Touhy Borst Component	9/6/2015	Arrow International Inc	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.