



## SBED Weekly Update

30-Sep-15

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 9/21/2015 to 9/27/2015  
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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**Dental devices**

New	Neoss Guide	9/27/2015	Neoss Australia Pty Ltd	N/A	2	<a href="#">A/CaV</a>
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**Diagnostic and therapeutic radiation devices**

#	Update	ADAC Vertex and Solus Gamma Camera Systems	9/24/2015	Philips Healthcare	Philips Healthcare Saudi Arabia	2	
#	New	AXIOM Artis X-ray Systems.	9/23/2015	SIEMENS	Siemens Medical Solutions	2	
	Update	Centricity PACS IW with Universal Viewer Version 5.0 and Centricity Universal Viewer Version 6.0 products	9/27/2015	GE Healthcare	GE Healthcare	FSN	<a href="http://nc.mdr.sfda">http://nc.mdr.sfda</a>

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New	Digital Radiography X-Ray Systems DR 400	9/22/2015	AGFA Corp.	Gulf Medical Co.	FSN	<a href="http://">http://</a>
New	Mobile Digital X-Ray GM60A GM60A-32S, GM60A-40S	9/25/2015	Samsung Electronics	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="http://nc">http://nc</a>
New	Monaco.	9/22/2015	Elekta Inc	or Medical and Scientific	1	<a href="A/CaV">A/CaV</a>
New	MR Surgical Suite II Table Transfer Release	9/27/2015	GE Healthcare	GE Healthcare	FSN	<a href="http://">http://</a>

### Electro mechanical medical devices

New	0.5 mL INFUSOR Patient Control Module Watches	9/22/2015	Baxter Healthcare	Baxter AG	2	<a href="http://">http://</a>	
New	4FR Single Lumen Pressure Injectable Peripherally Inserted Central Catheter (PICC)	9/22/2015	Teleflex Medical..	Gulf Medical Co.	1	<a href="http://ncmdr">http://ncmdr</a>	
#	New	CARTOSOUND Modules Used with SOUNDSTAR eco Catheters	9/22/2015	Biosense Webster Inc A Johnson & Johnson Co.	Saudi Import Co. Banaja	2	
New	Cuff Controller (Shiley Pressure Control)	9/22/2015	VBM Medical Inc	Al Khateeb United Trading Est.	FSN	<a href="http://">http://</a>	
#	Update	FX CorDiax 40, 50, ... 120 and FX CorDiax HDF600 dialysers	9/24/2015	Fresenius Medical Care	Saudi Renal Services Ltd.	FSN	
New	MATResponder Tourniquet	9/22/2015	Pyng Medical Corp.	N/A	FSN	<a href="http://">http://</a>	
New	MetaVision Suite Clinical Information Systems	9/23/2015	iMDsoft Ltd	N/A	2	<a href="http://">http://</a>	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Model 105109 HeartMate II LVAS System Pocket Controllers	9/22/2015	Thoratec Corp	Arabian Trade House Est.	2	<a href="http://nc">http://nc</a>
# New	Model P3930A 100 Low Beds	9/23/2015	Hill Rom Inc	Arabian Medical (Marketing Co. (AMCO	2	

### In vitro diagnostic devices

New	Ammonia Ultra Reagent	9/27/2015	SENTINEL CH. SpA	pplies & Services Co.Ltd	FSN	<a href="A/Ca">A/Ca</a>
New	cobas b 123 sensor cartridge BG/ISE/GLU/LAC	9/25/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	FSN	<a href="http">http</a>

### Laboratory equipment

New	Bulk Loader Module (BLM)	9/22/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	2	<a href="A/Ca">A/Ca</a>
New	EXACTAMIX compounder	9/21/2015	Baxter Healthcare	Baxter AG	FSN	<a href="A/Ca">A/Ca</a>

### Non-active implantable devices

New	Cranial Flap Tube Clamp and Crimping Device	9/27/2015	Synthes Inc	Isam Economic Co.	2	<a href="http">http</a>
New	Endo-Modell Tibiaplateau sets und Ersatzteilsets	9/25/2015	Pennine Healthcare	MEDICARE DRUG STORE COMPANY	FSN	<a href="http">http</a>
New	Medtronic Navigated Solera Driver Tips for Spinal Surgery	9/27/2015	Medtronic Inc	Gulf Medical Co.	2	<a href="http://nc">http://nc</a>
Update	Pin-sleeve orthopaedic bone screw, Dynamic Locking Screw Stardrive, 5 and 3.7mm	9/21/2015	Synthes Inc	Isam Economic Co.	FSN	<a href="http://nc">http://nc</a> <a href="mdr">mdr</a>
New	seleXys TH+ and seleXys TPS acetabular shells	9/22/2015	Mathys Ltd Bettlach	Isam Economic Co.	2	<a href="http">http</a>

### Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	ADULT-EDGE Electrodes with QUIK-COMBO Connector and REDI-PAK Preconnect	9/24/2015	Physio Control Inc	Al-Jeel Medical & Trading Co. LTD	2	

	New	Suction Adapter Type A (Gauge)	9/22/2015	Xcel Medical Solutions Pty Ltd	N/A	2	<a href="#">http:</a>
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### Single-use devices

#	New	ASP CIDEX Ortho-Phthalaldehyde (OPA) Solution	9/23/2015	Advanced Sterilization Products	FAROUK, MAAMOUN TAMER & COMPANY	2	
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#	New	Cardinal Health—Various Presource Kits Containing Hospira 1% Lidocaine HCl Injections	9/23/2015	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	
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#	New	Ecolab ORS Fluid Warming and Slush Drapes Contained in Medline Procedure Kits/Packs	9/24/2015	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	2	
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	New	MCS-Port Obturator / MCS5000	9/22/2015	Agency for Medical Innovations	N/A	FSN	<a href="#">http:</a>
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	New	PORT-A-CATH® Plastic Hub Needles	9/22/2015	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	FSN	<a href="#">http:</a>
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	New	Regard™	9/24/2015	ce Optimization & Innova	N/A	2	<a href="#">A/Ca\</a>
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#	New	resource Kits Containing Ecolab ORS Fluid Warming and Slush Drapes	9/24/2015	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	
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	New	Terumo Custom Cardiovascular Procedure Kit X-Coated.	9/21/2015	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	<a href="#">http://nc</a>
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- \* 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.