



**SBED Weekly Update** 23-Sep-15

Dear,  
SBED team is pleased to inform you that **74** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 9/13/2015 to 9/19/2015  
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
-----------	---------------	-----------	--------------	------------	-------	------

**Active Implantable Devices**

New	Temporary Total Artificial Heart (TAH-t) with Freedom Driver System	9/19/2015	SynCardia Systems Inc	Arabian Trade House Est.	1	<a href="http://nc.mdr">http://nc.mdr</a>
-----	---	-----------	-----------------------	--------------------------	---	---

**Anaesthetic and respiratory devices**

#	New	Two Medical Technologies Ventilation Timing Lights Used with SMART Bag Adults Ventilators	9/14/2015	Henry Schein, Inc	N/A	2	
---	-----	---	-----------	-------------------	-----	---	--

**Assistive products for persons with disability**

New	Maxi Air Blower Unit	9/15/2015	Huntleigh Healthcare.	Gulf Medical Co.	2	<a href="#">A/CaV</a>
New	Miniflex, Flexmobil, Forma	9/15/2015	Eurovema AB	N/A	1	<a href="#">A/CaV</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Pixi Sulki Stroller	9/13/2015	Eurovema AB	N/A	FSN	<a href="#">A/CaV</a>

### Dental devices

New	CA1:1L EVO 15	9/15/2015	William C. Domb, D.M.D	N/A	2	<a href="#">A/CaV</a>
New	UCLA Abutment Hexed Castable Cylinder 3.4mm	9/14/2015	Biomet 3i Inc	Asnan Medical Services	2	<a href="http://nc">http://nc</a>

### Diagnostic and therapeutic radiation devices

#	New	All Varian Oncology Products	9/16/2015	Varian Medical Systems	Varian Medical Systems	2	
#	New	Allura Xper X-Ray Systems	9/17/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	
#	Update	Brainlab Cranial Navigation System	9/15/2015	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	2	
	Update	Centricity PACS IW with Universal Viewer Version 5.0 and Centricity Universal Viewer Version 6.0 products	9/15/2015	GE Healthcare	GE Healthcare	FSN	<a href="http://nc.mdr.sfda.gov.s">http://nc.mdr.sfda.gov.s</a>
#	New	Echopulse High-Intensity Focused Ultrasound Therapy Systems	9/16/2015	Theraclion	N/A	2	
	New	Fluorescence Imaging Procedure Kits used with the da Vinci Si and Xi Surgical Systems	9/19/2015	Intuitive Surgical Inc	Gulf Medical Co.	2	<a href="http://nc.mdr.sfda">http://nc.mdr.sfda</a>
	New	GF-UCT180 Ultrasonic Gastrovideoscope	9/15/2015	Olympus	Salehiya Trading Est.	2	<a href="http://nc">http://nc</a>
#	New	Velocity Advanced Imaging Software	9/17/2015	Varian Medical Systems	Varian Medical Systems	2	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

## Electro mechanical medical devices

#	New	Alaris LVP Infusion Systems	9/14/2015	CareFusion 206 Inc,	Saudi Import Co. Banaja	2	
#	New	Bipolar and Monopolar Cables	9/15/2015	Zethon Ltd	N/A	2	
	New	Bodyguard 575 PCA Infusion Pump	9/15/2015	Caesarea Medical Electronics Ltd	N/A	FSN	<a href="http://nc">http://nc</a>
#	New	CARTO 3 System CARTO VISITAG Modules	9/16/2015	Biosense Webster Inc A Johnson & Johnson Co.	Saudi Import Co. Banaja	2	
	New	CDI 500 Blood Parameter Monitoring System	9/14/2015	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	<a href="http://nc">http://nc</a>
	New	Da Vinci Si Single-Site Gripping Instruments	9/14/2015	Intuitive Surgical Inc	Gulf Medical Co.	2	<a href="http://nc">http://nc</a>
#	New	Lumenis—VersaCut+ Tissue Morcellator Handpieces	9/16/2015	Lumenis Inc	ABDULREHMAN AL GOSAIBI GTB	1	
	Update	Lumenis—VersaCut+ Tissue Morcellator Handpieces	9/18/2015	Lumenis Inc	ABDULREHMAN AL GOSAIBI GTB	1	<a href="http://nc mdr">http://nc mdr</a>
#	New	M20 5001 multiFiltratePRO Dialysis Systems	9/15/2015	Fresenius Kabi Ltd	gulf Medical Co.	2	
	New	NICO Myriad Console	9/16/2015	Nico Corp	N/A	2	<a href="A/Ca">A/Ca</a>
	New	OFP-2 Flushing Pump Accessory- MAJ-1606 Instrument Channel	9/13/2015	Olympus	Salehiya Trading Est.	FSN	<a href="http://nc mdr">http://nc mdr</a>
#	New	Sterile Bipolar Forceps and Electrodes	9/16/2015	Zethon Ltd	N/A	2	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Temporary cardiac pacing wire	9/13/2015	Ethicon Endo Surgery Inc	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="http://nc">http://nc</a>
# New	Trumpf Ceiling Mounted Surgical Lighting Systems	9/15/2015	Trumpf Medical Systems, Inc.	Medical regulations gate	2	
# New	Various Guidewires ..	9/17/2015	Zimmer inc	Ebrahim M. Al-Mana	2	
New	Voyant Open Fusion Device	9/16/2015	Applied Medical Resources	Dawha Medical	2	<a href="http://nc">http://nc</a>

### Healthcare facility products and adaptations

# New	DuraPrep Surgical Solution Preoperative Skin Preparation	9/15/2015	3M Health Care Ltd	3M company	2	
-------	--	-----------	--------------------	------------	---	---

### In vitro diagnostic devices

New	ADVIA Chemistry XPT system..	9/13/2015	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="http://nc">http://nc</a>
# New	Calibrator A for T3 and T4 Assays Used with ADVIA Centaur Systems	9/15/2015	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	2	
# New	Dimension Reagent Probe Cleaners	9/15/2015	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
New	EnVision FLEX	9/17/2015	Dako Denmark A/S	Al-Zahrawi Medical Co. I	FSN	<a href="A/Ca">A/Ca</a>
New	HemoCue HbA1c 501	9/17/2015	Infopia Co., Ltd	ental System & Advanced	FSN	<a href="A/Ca">A/Ca</a>
New	Neopterin EIA	9/15/2015	BRAHMS	A FOUAD HOLDING COM	FSN	<a href="A/Ca">A/Ca</a>
New	Novocastra Reagent _ CD10-270-CE and CD10-270-CE-S	9/16/2015	Leica Biosystems Newcastle Ltd	medical business Center	FSN	<a href="http://nc mdr">http://nc mdr</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	RAPIDPoint® 500 System Measurement Cartridge Lactate	9/15/2015	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	<a href="http://ncmdr">http://ncmdr</a>
New	Various Remel Mueller-Hinton Broth	9/13/2015	Thermo Fisher...	AL-MOHANAD MEDICAL EST	FSN	<a href="http://nc">http://nc</a>

### Non-active implantable devices

	Update	Pedicle Awl 4.0mm w/Canevasit Handle ; Pedicle Awl 4.0mm w/Silicone Handle	9/15/2015	DePuy International Ltd	FAROUK, MAAMOUN TAMER & COMPANY	1	<a href="http://ncmdr.sfda">http://ncmdr.sfda</a>
#	New	16 mm Chisel Blades	9/14/2015	DePuySynthes	Isam Economic Co.	2	
	New	4 0 MM X 14 MM Variable Screw CTek Maxan Anterior Cervical Plate System	9/14/2015	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	<a href="http://ncmdr.sfda">http://ncmdr.sfda</a>
#	New	5.5 mm SpeedScrew Plus Kits	9/18/2015	Smith & Nephew Orthopaedic	Alhaya medical co.	2	
#	Update	Actifuse ABX and Actifuse MIS System	9/18/2015	Baxter Healthcare	Baxter AG	1	
	Update	ALIQUT Delivery System Complete Set	9/13/2015	Stryker Communications	Al-Faisaliah Medical System	2	<a href="http://nc">http://nc</a>
	New	Base array component of the MAKO RIO Robotic Arm	9/15/2015	Stryker Instruments	Al-Faisaliah Medical System	2	<a href="http://ncmdr">http://ncmdr</a>
	New	CIVCO Shoulder Retractors	9/16/2015	Med Tec Inc	Medical regulations gate	2	<a href="http://nc">http://nc</a>
	New	ConforMIS Knee Replacement Systems	9/17/2015	ConforMIS	N/A	FSN	<a href="http://nc">http://nc</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Endoskeleton Locking Bone Screw Assembly	9/16/2015	TITAN SPINE	N/A	2	<a href="#">Attached</a>
# New	LARIAT Suture Delivery Devices	9/15/2015	SentreHeart, Inc	N/A	1	
# New	ORS Fluid Warming and Slush Drapes	9/16/2015	Ecolab Inc	Al Hammadmedical Services	2	
# Update	ORS Fluid Warming and Slush Drapes	9/18/2015	Ecolab Inc	Al Hammadmedical Services	2	
# Update	S4C occiput torque wrench f/set screw	9/15/2015	Aesculap	Gulf Medical Co.	FSN	
# New	Sciatic Nerve Retractors	9/16/2015	DePuySynthes	Isam Economic Co.	2	
# New	UltOS Locking Screws	9/18/2015	Ortho Solutions	N/A	2	
New	Zimmer Natural Nail CM Long- Cephalomedullary Nails	9/17/2015	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="http://nc.mdr">http://nc.mdr</a>

### Ophthalmic and optical devices

New	ala octa	9/16/2015	lamedics GmbH & Co. KG	Saad Al Bashir	FSN	<a href="#">A/CA</a>
-----	----------	-----------	------------------------	----------------	-----	----------------------

### Reusable devices

# New	23 G and 25 G Valved Entry Systems	9/16/2015	Alcon Grieshaber AG	AL-KAMAL Import	2	
# New	8–10 mm Y Connectors	9/16/2015	Vygon UK Ltd	Jeel Medical & Trading	2	
# New	Sterile 60 mL EU BD Syringe Multi-Packs	9/14/2015	Ecolab Inc	Al Hammadmedical Services	2	
New	ThruPort Systems Knot Pusher	9/17/2015	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	FSN	<a href="http://nc">http://nc</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
	New	0.9% Sodium Chloride Injection	9/16/2015	Wolf Medical Supply	N/A	2	<a href="#">Attached</a>
#	New	100 mg/mL 5 mL Ketamine Hydrochloride Injection	9/17/2015	Hospira Inc	AL-KAMAL Import	2	
#	New	50 mL 0.9% Sodium Chloride Injections	9/14/2015	Hospira Inc	AL-KAMAL Import	2	
#	New	50 mL 0.9% Sodium Chloride Injections in VIAFLEX Plastic Containers and 100 mL 0.9% Sodium Chloride Injections in MINI-BAG Plus Containers	9/15/2015	Baxter Healthcare	Baxter AG	2	
#	New	Calcium Chloride Syringes	9/15/2015	Mylan Institutional	cigalah group	2	
#	New	Infant Heel Warmer and Infant Gel Warmer	9/15/2015	Cooper Surgical, Inc.	Cure Development International Ltd	2	
	New	Kimvent closed suction system	9/13/2015	Halyard Health Co.	N/A	2	<a href="http://nc">http://nc</a>
#	New	Kits Containing Medtronic Covidien 0.9% Sodium Chloride Flush Syringes	9/17/2015	Arrow International Inc	Gulf Medical Co.	2	
#	New	Pressure Monitoring Kits and Sets	9/17/2015	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	
#	New	Terumo SURFLO IV Catheters	9/17/2015	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	2	
	New	XGAUZE Trauma Dressing	9/14/2015	Revmedx Inc	N/A	2	<a href="#">A/Cal</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

- \* 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.