



**SBED Weekly Update** 02-May-17

Dear,  
SBED team is pleased to inform you that **40** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 4/24/2017 to 4/30/2017  
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	Distrbutor	Class	Link
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**Active Implantable Devices**

New	Pulsante SPG Microstimulator System	4/30/2017	Autonomic Technologies Inc. (ATI)	N/A	FSN	<a href="https://nc">https://nc</a>
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**Assistive products for persons with disability**

#	Update	LED Surgical Light	4/30/2017	Stryker Communications	I-Faisaliah Medical Syster	2	
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**Dental devices**

New	ImplantDriverProfile	4/25/2017	MPLANTS MANUFACTUR	Melat Trading.	FSN	<a href="#">A/Ca\</a>
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**Diagnostic and therapeutic radiation devices**

New	GC80	4/30/2017	Samsung Electronics	m M. Al-Mana & Bros. Co	FSN	<a href="#">A/Ca\</a>
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**Electro mechanical medical devices**

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Cart-Mounted Computer Systems	4/24/2017	PENTAX Medical	Al Amin Medical Instruments Co. Ltd.	2	<a href="#">Attached</a> 
	New	EP-TRACER	4/30/2017	chwarzer Cardiotek GmbH	Bio Standards	FSN	<a href="#">A/Cal</a>
#	Update	Merlin@home Monitoring Transmitters Used with Radio-Frequency-Enabled Implantable Cardiac Devices	4/24/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	
#	New	Moisture Trap Filters Used with Capnocheck Sleep Capnograph Systems	4/30/2017	Smiths Medical, Inc	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attached</a> 
#	New	SERIE 3 GTA Endoscope Washer-Disinfectors	4/30/2017	Soluscope	Techno-Orbits Establishment	2	<a href="#">Attached</a> 
#	New	Smiths Moisture Trap Filters Used with Capnocheck Sleep Capnograph Systems	4/30/2017	Tri anim Health Services Inc	N/A	2	<a href="#">Attached</a> 
<b>In vitro diagnostic devices</b>							
#	New	15 µg Telithromycin Cartridge Disks	4/24/2017	MAST International Ltd	Al Nahir Trading Co	2	<a href="#">Attached</a> 
	Update	Access 2 Immunoassay System,	4/30/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	<a href="https://nc">https://nc</a>
#	New	ADVIA Centaur Systems Insulin Calibrators and ReadyPack Kits	4/30/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	<a href="#">Attached</a> 
	New	AQUIOS CL Cytometer	4/30/2017	Beckman Coulter	el Medical & Trading Co.	FSN	<a href="#">A/Cal</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Dimension® EXL™ integrated chemistry system, Dimension Vista® System & Dimension EXL TNI, Dimension Vista DIGXN, E2, FERR, PRL, TSH	4/30/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https://ncmdr.sfda.gov.sa/Secure/">https://ncmdr.sfda.gov.sa/Secure/</a>
New	Etest ERTAPENEM ETP 32	4/30/2017	bioMerieux Inc	el Medical & Trading Co.	FSN	<a href="#">A/CA\</a>
New	RAPIDPoint® 500 Systems Blood Gas Analyzer	4/30/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	<a href="https://ncmdr.">https://ncmdr.</a>
New	Synchron Systems Cholesterol, Creatinine, HDL Cholesterol, Lactate, Triglyceride, Uric Acid and Salicylate Reagents	4/30/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
Update	VITROS Chemistry Products Na+ Slides	4/30/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	<a href="https://nc">https://nc</a>

### Non-active implantable devices

#	Update	LFIT V40 Femoral Heads.	4/24/2017	Stryker Orthopaedics	hmo Trading Establishme	2		
	New	Modular neck with taper 10/12, Modular neck with taper 12/14, ACOR modular anatomic femoral stem, INTEGRALE modular femoral stem and OPTIMAL modular femoral stem	4/30/2017	Amplitude GmbH	N/A	FSN	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec</a>	
	New	Standard Lag Screw Omega	4/25/2017	Stryker Trauma AG	Al-Faisaliah Medical System	FSN	<a href="https://nc">https://nc</a>	

### Ophthalmic and optical devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Healon Ophthalmic Viscoelastic Devices	4/30/2017	Abbott Medical Optics Inc.	Gulf Medical Co.	2	<a href="#">Attac hed</a> 

### Reusable devices

	New	Flexible Video Duodenoscope	4/30/2017	Olympus	Salehiya Trading Est.	FSN	<a href="https://nc">https://nc</a>
#	New	Hi-Line and ELAN 4 Diamond Burrs	4/24/2017	Aesculap	Gulf Medical Co.	2	<a href="#">Attac hed</a> 
	New	Hot water bag with cover.	4/30/2017	ANGHAI NINELUCK CO.L	meidan and khowaiter c	FSN	<a href="#">A/Ca\</a>
#	New	Inflatoball Pessaries and Pessary Kits	4/30/2017	Cooper Surgical, Inc.	Cure Development International Ltd	2	<a href="#">Attac hed</a> 
#	New	Pereyra Ligature Carriers, Pereyra-Raz Ligature Carriers, and Stamey Needles	4/30/2017	Cook Inc,	NAFA Medical	2	<a href="#">Attac hed</a> 

### Single-use devices

#	New	150 cm Semislip Guidewires	4/30/2017	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	2	<a href="#">Attac hed</a> 
#	New	5 mL Luer Lock IV Syringes	4/30/2017	Medicina	Al Hammad Medical Services	2	<a href="#">Attac hed</a> 
	New	ARROW Kits with BD Eclipse Needles	4/30/2017	Arrow International Inc	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
	New	DOLPHIN Inflation Device, CALIBER Inflation Device	4/25/2017	Perouse Medical	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc.mdr">https://nc.mdr.</a>
#	New	Elcam CytoGuard Closed Luer Connectors	4/30/2017	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	<a href="#">Attac hed</a> 
	New	Hang&Go kits, HIPP(F)	4/30/2017	RanD S.r.l.	Gulf Medical Co.	FSN	<a href="#">A/Ca\</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Jackson-Pratt Perforated and Hemaduct Wound Drainage Systems	4/30/2017	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attac hed</a>
# New	Minimal Residual Volume Luer-Activated Swabable Stopcocks	4/30/2017	Elcam Medical Inc	N/A	2	<a href="#">UCA</a>
# New	Monoswift PGCL Absorbable Sutures	4/30/2017	C P Medical	N/A	2	<a href="#">UCA</a>
New	OPTILENE 8/0 (0,4) 60CM 2XDR8	4/25/2017	B Braun Surgical SA	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
# New	Rythmic Parenteral Nutrition DEHP-Free Spike Sets	4/30/2017	Micrel Medical Devices S.A.	Techno-Orbits Establishment	2	<a href="#">Attac hed</a>
# New	Saflo 90 Needle Safe Subcutaneous Infusion Sets	4/30/2017	Applied Medical Technology,Inc	NOORI MARZOOQ TRAD EST	2	<a href="#">Attac hed</a>

\* 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.