



**SBED Weekly Update** 21-Aug-17

Dear,  
SBED team is pleased to inform you that **52** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 8/14/2017 to 8/17/2017  
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	Various S-ICD Systems	8/16/2017	Boston Scientific Ltd	MAAMOUN TAMER & Co	2	<a href="#">A/Call</a>
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**Anaesthetic and respiratory devices**

#	New	Breathing Sets with APL Valves	8/16/2017	Meditech Systems	N/A	2	<a href="#">Attached</a>
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	New	Disposable Expandable Adult 22mmID Expandable Anaesthetic Circuits	8/17/2017	Mediplas Respiratory Products Sdn Bhd	N/A	2	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
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**Assistive products for persons with disability**

#	Update	Universal Arm Support	8/16/2017	umpf Medical Systems, Inc	Medical regulations gate	FSN	<a href="#">Attached</a>
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**Dental devices**

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	tra-System/ Legacy Guided Surgery Handle Kit	8/17/2017	Implant Direct LLC	N/A	FSN	<a href="https://nc.mdr">https://nc.mdr</a>

### Diagnostic and therapeutic radiation devices

#	New	ARTIS Pheno Systems ,	8/16/2017	SIEMENS	iemens Medical Solution	2	<a href="#">ttache</a> 
	New	Radrex-i	8/16/2017	a Medical Systems Corpo	Gulf Medical Co.	FSN	<a href="#">A/Cal</a>
	New	Rigid Arm Support	8/17/2017	yco Medical Instruments In	Majal Care for Trading Est	FSN	<a href="#">A/Cal</a>

### Electro mechanical medical devices

	New	ARCTIC SUN® 5000 Temperature Management System	8/15/2017	C R Bard Inc	C.R. BARD Saudi Arabia	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
	New	BeneFusion VP1, BeneFusion VP3 infusion pump	8/16/2017	Shenzhen Mindray	Salehiya Trading Est.	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
	New	BEO NC PTCA Catheters	8/14/2017	SIS Medical AG	N/A	2	<a href="#">A/Cal</a>
	New	Cell Saver Elite	8/14/2017	Haemonetics Corp	d Abdul Jalil Al Fadhli & S	FSN	<a href="#">A/Cal</a>
	New	Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology	8/15/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
	New	Fogarty Adherent Clot Catheter	8/14/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	FSN	<a href="https://nc">https://nc</a>
#	Update	NovoPen Echo	8/16/2017	Novo Nordisk	Novo Nordisk	2	<a href="#">ttache</a> 
#	New	OneStep CPR Complete Adult Electrodes	8/14/2017	ZOLL Medical Corp	Al Hammad Medical Services	2	<a href="#">Attac</a> <a href="#">hed</a> 

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	PLEGIOX Cardioplegia Heat Exchanger	8/14/2017	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	<a href="https://nc">https://nc</a>
# New	ROSA Surgical Systems ,	8/15/2017	Zimmer Biomet	n Medical Instruments Co	2	<a href="ttache">ttache</a>
New	ThermaSure(TM), a CENORIN(TM) product, 1000 Series, 130 Series, 300 Series	8/15/2017	Cenorin	N/A	2	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
New	Ultrasound Upper GI Video Scopes	8/17/2017	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd	2	<a href="https://nc">https://nc</a>

### Healthcare facility products and adaptations

New	S7XTRA Concentrate 5 Litre bottles	8/17/2017	Safapac Ltd	N/A	2	<a href="https://nc">https://nc</a>
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### In vitro diagnostic devices

New	Abbott RealTime HIV-1 Assay ,	8/17/2017	Abbott	Medical supplies & Services Co.Ltd	2	<a href="https://nc">https://nc</a>
New	Gentian Cystatin C Calibrator Kit.	8/17/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	<a href="https://nc">https://nc</a>
New	Human IgM kit for use on SPAPLUS ,	8/17/2017	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https://nc">https://nc</a>
New	IgE Calibrator Series	8/17/2017	Randox Laboratories Ltd.	Bio Standards	2	<a href="A/Ca">A/Ca</a>
New	ipsogen..	8/14/2017	QIAGEN Ltd	A FOUAD HOLDING COM	FSN	<a href="A/Ca">A/Ca</a>
New	PreciControl Universal	8/16/2017	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	<a href="A/Ca">A/Ca</a>
# New	Remel E. coli Polyvalent and Monovalent Agglutinating Sera	8/16/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	2	<a href="Attached">Attached</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	UniCel DxH Slidemaker Stainer Coulter Cellular Analysis Systems	8/15/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	<a href="#">Attached</a>

New	VITROS Performance Verifier II	8/17/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	<a href="https://nc">https://nc</a>
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### Medical software

New	Oncentra® Brachy	8/15/2017	Nucletron bv	Medical regulations gate	FSN	<a href="#">A/Cal</a>
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# Update	SoftLab Software ,	8/16/2017	SCC Soft Computer	N/A	2	<a href="#">ttache</a>
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### Non-active implantable devices

New	Affinis CoCr head 43/15/2	8/14/2017	Mathys Ltd Bettlach	Isam Economic Co.	FSN	<a href="#">A/Cal</a>
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New	Arthroline Stanze B 4,6MM H1,6MM	8/16/2017	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc">https://nc</a>
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New	balanSys RP Tibial Plateau TiNbN	8/14/2017	Mathys Ltd Bettlach	Isam Economic Co.	FSN	<a href="https://nc">https://nc</a>
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New	CESPACE PEEK TRIAL IMPLANT 5° 16X12MM ANAT	8/16/2017	Aesculap	Gulf Medical Co.	FSN	<a href="https://nc.mdr">https://nc.mdr.</a>
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New	D-Rad Titanium 2.4mm x 10mm Locking Screw T7 Self-Tapping	8/17/2017	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc.mdr">https://nc.mdr.</a>
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New	Dualswitch Valve (DSV)	8/15/2017	toph Miethke GmbH & Co	N/A	FSN	<a href="#">A/Cal</a>
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# New	Matrix Screws ,	8/16/2017	DePuy Ireland UC	Johnson Medical Saudi Ar	2	<a href="#">ttache</a>
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# New	New Generation RM Classic Flexible Reaming Shafts and Countersink Reamers	8/16/2017	Mathys Ltd Bettlach	Isam Economic Co.	2	<a href="#">Attached</a>
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New	Polarstem Cardan for 21000438	8/17/2017	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc">https://nc</a>
New	VEGA PS TIBIA-PROBE- /PRÄPARIERPLAT.T4	8/16/2017	Aesculap	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
# New	Versys Beaded Hip Stems and Segmental Knee Products	8/16/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="https://nc.mdr">https://nc.mdr</a>
New	Zugschraube	8/15/2017	Litos GmbH	N/A	FSN	<a href="#">A/Ca\</a>

### Single-use devices

# New	Nit-Occlud Implantation Sheaths	8/16/2017	pfm medical ag, pfm medical mepro	Medical Technology Establishment	2	<a href="#">Attach</a>
# New	Arrow Advantage 5 Pressure-Injectable PICC Kits	8/15/2017	Arrow International Inc	Gulf Medical Co.	2	<a href="#">Attach</a>
# New	BD SafetyGlide Needles Contained in Arrow Arterial Catheterization Kits	8/16/2017	Arrow International Inc	Gulf Medical Co.	2	<a href="#">Attach</a>
# New	Bridge Occlusion Balloons	8/15/2017	Spectranetics Corporation	Almarfa Medical	2	<a href="#">ttache</a>
# New	LLA300-F/FB/N Flexible Catheters	8/16/2017	Ecken & Ziegler BEBIG GmbH	N/A	2	<a href="#">Attach</a>
# New	REVOLVE Advanced Adipose Systems	8/16/2017	Allergan services international Limited	Cigalah Group	2	<a href="#">Attach</a>
# Update	VueOptic Visualisation Source & Flexor Vue Deflecting Endoscopic System	8/15/2017	Cook Medical	NAFA Medical	2	<a href="#">Attach</a>
# New	XRO Umbilical Catheters	8/15/2017	Vygon UK Ltd	el Medical & Trading Co.	2	<a href="#">A/CaV</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.