



SBED Weekly Update 21-Nov-17

Dear,

SBED team is pleased to inform you that **31** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/13/2017 to 11/19/2017
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

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	Heparin-Coated Guidewires and Catheter Sets	11/14/2017	Cook Medical	NAFA Medical	2	Attached

	New	SynchroMed II Implantable Drug Infusion Pump.	11/16/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
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Anaesthetic and respiratory devices

	New	Breas Vivo 60.	11/16/2017	Medical AB A GE Healthc	R HEALTHCARE SAUDI A	FSN	A/Cal
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Assistive products for persons with disability

	New	Compella Air Surfaces Bed System (220 - 240 V, 50 Hz),	11/19/2017	Hill Rom Inc	Medical regulations gate	2	https://nc
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Diagnostic and therapeutic radiation devices

Update	Accent/ Anthem, Accent MRI/ Accent ST, Assurity/ Allure and Assurity MRI devices	11/19/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr
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#	New	Bair Hugger Temperature Monitoring Sensors	11/14/2017	3M Health Care Ltd	3M company	2	https
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New	Brilliance ICT, Brilliance iCT SP, IQon Spectral CT	11/16/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https
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#	New	Edan F-Series Fetal Monitor Insight Software	11/14/2017	Cooper Surgical, Inc.	Cure Development International Ltd	2	Attac
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#	New	Infant/Child Reduced Energy Defibrillation Electrodes Used with LIFEPAK Automatic External Defibrillators	11/14/2017	Physio Control Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc.mdr.sfda
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New	mint Lesion	11/16/2017	Mint Medical GmbH	N/A	FSN	A/Ca
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#	New	Model 3120 ZOOM LATITUDE Programmer/Recorder/Monitor Systems	11/14/2017	Boston Scientific Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac hed
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#	New	Situate Gauze	11/14/2017	Medtronic SA	Medtronic Saudi Arabia	2	ttache
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New	SOMATOM Force, SOMATOM Definition AS, Edge, Flash	11/16/2017	SIEMENS	Siemens Medical Solutions	FSN	https://nc
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New	Xray Cabinet Models	11/13/2017	North Star Imaging Inc	N/A	2	A/Ca
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Electro mechanical medical devices


New	Acetabular Cup Introducer	11/16/2017	DePuy Ireland UC	Johnson Medical Saudi Ar	2	A/Ca
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Sorin Group perfusion system – Heater Cooler 1T devices	11/16/2017	LivaNova Deutschland GmbH.	Arabian Trade House Est.	1	https://nc
New	Sorin Group perfusion system – Heater Cooler 3T devices	11/16/2017	LivaNova Deutschland GmbH.	Arabian Trade House Est.	1	https://nc

Healthcare facility products and adaptations

#	New	Bow Frames	11/14/2017	Allen Medical Systems	Alwasat for Trading Cor	2	ttache 
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In vitro diagnostic devices

New	CLINITEK Novus to Atellica UAS 800 Rack Handler	11/16/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	https://nc	
New	cobas MRSA/SA Nucleic acid test for use on the cobas Liat System	11/16/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc	
Update	Dimension Vista Hemoglobin A1c (HbA1c)	11/19/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	1	https	
New	DxH 500 Open-Vial Haematology System	11/19/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	https	
#	New	Remisol Advance Software Versions Used with Abbott Architect Instruments	11/14/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	Attched 

Laboratory equipment

New	Thermofisher Remel Bactipstaph Latex Kits	11/19/2017	Remel Inc.	Medical supplies & Services Co.Ltd	2	https
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Non-active implantable devices

New	Disposable Reuter Tip-Deflecting Wire Guide	11/19/2017	William Cook Europe ApS	NAFA Medical	2	https
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Ophthalmic and optical devices

New	1-DAY ACUVUE MOIST Brand Contact Lenses	11/16/2017	Johnson & Johnson Vision Care	Allied Medical International	FSN	https://ncmdr
New	Small intestinal videoscope SIF-Y0019 and Single use Spiral tube ST-Y0008	11/16/2017	Olympus	Salehiya Trading Est.	FSN	https://ncmdr


Reusable devices

New	Reservoir Bag for Infusion Pump	11/16/2017	WalkMed Infusion, LLC	N/A	2	https://ncmdr
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Single-use devices

#	New	0.9% Sodium Chloride Injections in 100 mL VIAFLEX Plastic Container Quad Packs	11/14/2017	Baxter Healthcare	Baxter AG	2	Attached
#	New	Arrow Radial Artery Catheterization Kits and Arrow Arterial Access Trays Containing Medline/Apicare Povidone Iodine Prep Pads	11/14/2017	Teleflex Medical..	Gulf Medical Co.	2	Attached
	New	CADD Medication Cassette Reservoir	11/16/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	https://ncmdr

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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.