



SBED Weekly Update 14-Aug-17

Dear,

SBED team is pleased to inform you that **24** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/7/2017 to 8/13/2017
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	Platinum Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	8/7/2017	Sorin Group	Arabian Trade House Est.	FSN	https://ncmdr.sfda.gov.s
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Assistive products for persons with disability

New	leg bag	8/13/2017	C R Bard Inc	C.R. BARD Saudi Arabia	2	A/Cal
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Diagnostic and therapeutic radiation devices

#	New	AMULET Digital Mammography Systems	8/10/2017	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac
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New	SIGNA, Brivo, Optima MRI	8/13/2017	GE Healthcare	GE Healthcare	2	A/Cal
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	VANTA Analytical X-Ray System, X-Ray Fluorescence	8/9/2017	Olympus	Salehiya Trading Est.	2	https://nc

Electro mechanical medical devices

#	New	Medfusion Syringe Pumps ,	8/10/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	Attac	
#	New	Model 24950 and Model 25000 MyCareLink Remote Monitors	8/9/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	Attac	
#	New	Post-Auricular Cables Used with 2000 Ventricular Assist Systems	8/10/2017	Jarvik Heart Inc	N/A	2	Attac	

In vitro diagnostic devices

	New	N-Antiserum to Human Ig/L-chain, Lambda-type	8/7/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	https	
#	New	VFM Coverslips and Slides	8/13/2017	CellPath	N/A	2	ttache	
	New	VIDAS Testosterone ,	8/7/2017	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Cal	

Non-active implantable devices

#	New	CORAIL Collarless Stem Prostheses ,	8/10/2017	DePuy International Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac	
	New	Manual Surgical Instrument	8/13/2017	Exactech	N/A	2	https	
	New	MAXIMIS Pedicle Screw Spinal Fixation System	8/13/2017	Valorem Surgical LLC	N/A	2	https	
#	New	Sterile Reaming Rods and Light Clips	8/10/2017	DePuy Spine, Inc.	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac	


Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Cardiopulmonary Bypass Catheter Cannula and Tubing	8/13/2017	Sorin Group	Arabian Trade House Est.	2	https://nc
New	Percuvance® Percutaneous Surgical System	8/7/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https://nc
New	pneumo cryo probes for ERBECRYO 2	8/7/2017	ERBE Elektromedizin GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	https

Single-use devices

#	New	1,000 mL 0.9% Sodium Chloride Injections ,	8/10/2017	Hospira Inc	AL-KAMAL Import	2	Attac 
	New	2010 Video Guided Catheter	8/9/2017	Myelotec, Inc.	N/A	2	https
#	New	3.2 mm Vix Bits	8/13/2017	xatech Deutschland GmbH	N/A	2	ttache 
#	New	Baxter Non-DEHP INTRAVIA Medication Delivery Bags	8/9/2017	Baxter Healthcare	Baxter AG	2	Attac hed 
	New	Stroke Fast Pack	8/9/2017	Stryker Neurovascular	MAAMOUN TAMER & C	2	A/Cal
#	New	Tuohy Epidural Needles	8/10/2017	Epimed International Inc	Pioneer Medical Company	2	ttache 

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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.