



SBED Weekly Update 25-Apr-17

Dear,
SBED team is pleased to inform you that **47** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 4/17/2017 to 4/23/2017
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	Various Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy Defibrillators	4/17/2017	Sorin	Arabian Trade House Est.	2	Attac hed

Anaesthetic and respiratory devices

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	GlaxoSmithKline 200 Dose Ventolin HFA Albuterol Inhalers	4/17/2017	GlaxoSmithKline Consumer Healthcare	Ahmed Mohammed Abdulwahab Naghi & Sons	2	Attac hed

Assistive products for persons with disability

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	Bath Chairs	4/23/2017	Smirthwaite Ltd	N/A	2	ttache
	New	Ferno PROFlexx Model 28Z Chair Cot	4/18/2017	Ferno-Washington Inc	Al Hammad Medical Services	2	https

Complementary therapy devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	GHIATAS Beaded Breast Localization Wires	4/17/2017	C R Bard Inc	C.R. BARD Saudi Arabia	2	Attac

Dental devices

	New	Keystone Dental PrimaConnex Straight Implant TC	4/18/2017	Keystone Dental Inc	Masat Alteb	2	https://nc
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Diagnostic and therapeutic radiation devices

#	New	CT Express Injector Units	4/23/2017	BRACCO Diagnostics Inc	N/A	2	
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#	New	MAGNETOM Aera, Prisma, Skyra, and Spectra Magnetic Resonance Imaging Systems	4/23/2017	Siemens Medical Solutions	Siemens Medical Solutions	2	Attac hed
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#	New	Power Supplies Used with Fujifilm FCR XG-1 Computed Radiography Systems	4/18/2017	Christie Innomed	N/A	2	Attac hed
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	New	Proteus Plus	4/18/2017	IBA Dosimetry GmbH	I-Faisaliah Medical Syster	2	A/Cal
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#	New	Symbia Intevo Systems ,	4/17/2017	SIEMENS	iemens Medical Solution	2	ttache
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Electro mechanical medical devices

#	New	Absorb GT1 Bioresorbable Vascular Scaffold Stents	4/17/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	2	Attac hed
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#	New	ARCTIC SUN 5000 Temperature Management Systems	4/17/2017	C R Bard Inc	C.R. BARD Saudi Arabia	2	Attac hed
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#	New	Bipolar Forceps	4/17/2017	Accuscience	N/A	2	ttache
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#	New	GlideScope GVL 2 Stat Blades Used with GlideScope Video Baton 1-2 Systems	4/17/2017	Verathon Inc	Techno-Orbits Establishment	2	Attac hed
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	HeartWare Ventricular Assist Device Controllers and Heart Ware 1435 DC Adapters	4/17/2017	Medtronic SA	Medtronic Saudi Arabia	2	Attached
# New	IntelliSpace and Xcelera Information Management Systems	4/17/2017	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	2	Attached
# New	Reusable ATAR Extension Cables	4/17/2017	Oscor Inc.	Medical Technology Establishment	2	Attached
# New	Saline Infusion Pumps	4/23/2017	Cardiovascular Systems, In	N/A	2	Attached

Healthcare facility products and adaptations

# New	Allura Xper Connect Hospital Information Systems (HIS)	4/17/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attached
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In vitro diagnostic devices

New	Access Ferritin Calibrators for Access Ferritin assay on the Access Immunoassay Systems	4/18/2017	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	2	https://nc.mdr
# New	ACCU-CHEK Inform II Blood Glucose Meters	4/23/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attached
# New	ACQUITY UPLC Sample Organizers	4/23/2017	Waters Corporation,	Bio Standards	2	Attached
New	ARCHITECT SHBG Reagents.	4/19/2017	Abbott	Medical supplies & Services Co.Ltd	FSN	https
# New	Cascade Abrazo c-ACT-LR Cards	4/18/2017	Helena Laboratories	Arabian Trade House Est.	2	Attached
# New	enGen Laboratory Automation Systems Using TCAutomation Software with InOut Communication Interface	4/18/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	Attached

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	LeadCare Blood Lead Testing Systems	4/17/2017	Magellan Diagnostics Inc	N/A	2	Attac
#	New	Mylan EpiPen and EpiPen Jr Autoinjectors	4/18/2017	Meridian Bioscience Inc	ABDULLA FOUAD HOLDING COMPANY	2	Attac
#	New	OSOM BVBLUE Test Kits	4/18/2017	Sekisui Diagnostics	pplies & Services Co.Ltd	2	ttache
#	New	PreciControl Varia Level 0 Reagents Used with Elecsys PTH and PTH STAT Immunoassay Systems	4/23/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac hed
#	New	proBNP II and proBNP II Stat Reagents .	4/17/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac
#	New	Various Synchron Systems Reagents ,	4/18/2017	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	2	Attac

Laboratory equipment






#	New	Varian TV 801 Turbo Pumps on API 4000, 4000 QTRAP, and API 5000 Mass Spectrometer Systems	4/17/2017	AB SCIEX Pte. Ltd	Bio Standards	2	Attac hed
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Non-active implantable devices


	New	Soft Face "No Bounce" Mallet	4/18/2017	Signal Medical Corporation	N/A	2	https
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Reusable devices

#	New	ACUFEX TRUNAV Retrograde Drills	4/18/2017	Smith & Nephew	Alhaya medical co.	2	Attac
#	New	Air/Water and Suction Buttons on GI Endoscopes	4/23/2017	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	2	Attac
	New	Hemotherm CE, model 400CE, HeaterCooling Device	4/18/2017	Cincinnati Sub-Zero Products Inc	Al Shoumoukh Trading for Technical and Medical Supplies	2	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	SURESTEP Foley Catheter Tray Systems with BARDEX I.C. COMPLETE CARE Drainage Bags	4/17/2017	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	Attac hed 
#	New	WECK Visistat 35R Skin Staplers	4/17/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	Attac hed 
Single-use devices							
#	New	AirLife Modudose 0.9% Sodium Chloride Solution Vials	4/17/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	2	Attac hed 
#	New	B Braun APEX 26-Lead Transfer Sets	4/23/2017	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	Attac hed 
#	New	HeartMate II System Pocket Controllers	4/18/2017	Thoratec Corp	Arabian Trade House Est.	2	Attac hed 
#	New	IrisFIT Patent Foramen Ovale Occluders	4/23/2017	Lifetech Scientific (Shenzhen) Co.,Ltd..	Medtronic Saudi Arabia	2	Attac hed 
#	New	Multi-Organ Procurement Catheters ,	4/17/2017	Coloplast A/S	Al Hammad Medical Services	2	Attac hed 
#	New	Post-Op Eye Tray Convenience Kits Containing Covidien Curity Oval Eye Pads	4/17/2017	Centurion Medical Products	Bio Standards	2	Attac hed 
#	New	SENSATION PLUS Intra-Aortic Balloon Catheters with Insertion Kits and STATLOCK	4/23/2017	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	2	Attac hed 
#	New	Various Dressings	4/23/2017	Breg Inc	N/A	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.