



SBED Weekly Update

02-Oct-18

Dear,

SBED team is pleased to inform you that **44** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 9/25/2018 to 9/30/2018
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
------	---------------	-----------	--------------	------------	-------	------	-----------------

Assistive products for persons with disability

#	New	Hexapod Struts	9/26/2018	Stryker Europe	I-Faisaliah Medical Syster	FSN	ttache	
---	-----	----------------	-----------	----------------	----------------------------	-----	------------------------	--

Dental devices

New	Diverse Dentalimplantate	9/27/2018	Victory Implants	N/A	FSN	A/Cal	
-----	--------------------------	-----------	------------------	-----	-----	-----------------------	--

Diagnostic and therapeutic radiation devices

New	fMRI Hardware System VisualSystem	9/25/2018	NordicNeuroLab Inc.	N/A	2	https	
-----	--------------------------------------	-----------	---------------------	-----	---	-----------------------	--

New	Ashland(TM) Box Film Ball Cube II EBT3	9/27/2018	Accuray Inc	Gulf Medical Co.	2	https	
-----	---	-----------	-------------	------------------	---	-----------------------	--

Update	CoaguChek (XS PT, XS PT PST, and PT) strips	9/26/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANYY	FSN	https	
--------	--	-----------	------------------------	-------------------------------------	-----	-----------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Codan Filter, Medrad Patient Administration Sets, Intego Infusion Systems	9/26/2018	Bayer Healthcare LLC..	Scientific & Medical Equipment House	FSN	Attac hed	

New	ddR Formula B X-ray System	9/26/2018	Swissray	Saudi Health Services Co. Ltd.	2	https	
-----	----------------------------	-----------	----------	--------------------------------	---	---------------------------	--

New	Millennium MG, Millennium MC, Millennium MYOSIG	9/30/2018	GE Healthcare	GE Healthcare	FSN	https://nc	
-----	---	-----------	---------------	---------------	-----	-------------------------------------	--

New	O-arm 1000 Surgical Imaging System	9/30/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
-----	------------------------------------	-----------	--------------	------------------------	-----	---------------------------	--

New	Overhead Counterpoise Systems (OCS)	9/25/2018	Bayer Healthcare LLC..	Scientific & Medical Equipment House	2	https	
-----	-------------------------------------	-----------	------------------------	--------------------------------------	---	---------------------------	--

New	VidiStar(TM) PACS & DICOM Viewer Software system	9/25/2018	Hitachi Medical Corp	ABDULREHMAN AL GOSAIBI GTB	2	https://nc	
-----	--	-----------	----------------------	----------------------------	---	-------------------------------------	--

Electro mechanical medical devices

New	220-240V Unit Cable (power cord) for Infusomat fmS, Infusomat P and SpaceCover	9/26/2018	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc.mdr	
-----	--	-----------	---------------------	---	-----	---	--

New	ALTRIX, 220-240V/50HZ	9/27/2018	Stryker Instruments.	hmo Trading Establishme	FSN	A/Cal	
-----	-----------------------	-----------	----------------------	-------------------------	-----	---------------------------	--

New	Giraffe OmniBed	9/27/2018	GE Healthcare	GE Healthcare	FSN	A/Cal	
-----	-----------------	-----------	---------------	---------------	-----	---------------------------	--

New	Giraffe OmniBed Carestation, Giraffe Incubator Carestation, Giraffe Warmer, Panda iRes Warmer, Panda Freestanding Warmer and Panda Wall Mount	9/27/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr.sfda.gov.sa/Sec	
-----	---	-----------	---------------	---------------	-----	---	--

New	Makoplasty RIO Standard System	9/25/2018	MAKO Surgical Corp	N/A	2	https	
-----	--------------------------------	-----------	--------------------	-----	---	---------------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Orbital Atherectomy System (OAS) Saline Infusion Pump ,	9/25/2018	Cardiovascular Systems, Inc	N/A	2	https://nc	

Hospital hardware

New	IsoFlex LAL Support Surface	9/25/2018	Stryker	Al-Jeel Medical & Trading Co. LTD	2	https	
-----	-----------------------------	-----------	---------	-----------------------------------	---	---------------------------	--


New	PR1000 Pivot Rehab Bed AC powered adjustable bed.	9/26/2018	Med-Mizer, Inc.	N/A	2	https://nc	
-----	---	-----------	-----------------	-----	---	-------------------------------------	--

In vitro diagnostic devices

New	Alere DDS2 Test Kit	9/30/2018	Alere	chno-Orbits Establishme	FSN	A/Cal	
-----	---------------------	-----------	-------	-------------------------	-----	---------------------------	--

#	New	Alere NT-proBNP for ARCHITECT Controls	9/27/2018	Axis-Shield Diagnostics Limited	Medical supplies & Services Co.Ltd	FSN	Attac	
---	-----	--	-----------	---------------------------------	------------------------------------	-----	---------------------------	---

New	CHOLESTEROL-HDL Direct ,	9/30/2018	BIOLABO	Semac company Est.	FSN	https	
-----	--------------------------	-----------	---------	--------------------	-----	---------------------------	--

#	New	Clear & Simple Digital Pregnancy Tests	9/27/2018	GUANGZHOU Wondfo Biotech Co., Ltd.	Regulatory Standards	FSN	Attac	
---	-----	--	-----------	------------------------------------	----------------------	-----	---------------------------	---

New	Contour Plus Link 2.4 ,	9/26/2018	Medtronic SA	Medtronic Saudi Arabia	2	A/Cal	
-----	-------------------------	-----------	--------------	------------------------	---	---------------------------	--

New	FlexLab ,	9/30/2018	Inpeco S.A.	pplies & Services Co.Ltd	FSN	A/Cal	
-----	-----------	-----------	-------------	--------------------------	-----	---------------------------	--

New	Kaluza C Flow Cytometry	9/30/2018	Beckman Coulter...	an Coulter Saudi Arabia	FSN	A/Cal	
-----	-------------------------	-----------	--------------------	-------------------------	-----	---------------------------	--

New	THIOGLYCOLLATE MEDIUM ,	9/25/2018	Remel Inc.	Medical supplies & Services Co.Ltd	2	https	
-----	-------------------------	-----------	------------	------------------------------------	---	---------------------------	--

New	URO-3 Triple Stain (CD44 + p53) with CK20,	9/26/2018	Biocare Medical Llc	Basic Electronics Company Ltd	2	https	
-----	--	-----------	---------------------	-------------------------------	---	---------------------------	--

Medical software

#	New	Radimetrics Enterprise Platforms	9/27/2018	Bayer Healthcare LLC..	Scientific & Medical Equipment House	FSN	Attac	
---	-----	----------------------------------	-----------	------------------------	--------------------------------------	-----	---------------------------	---

Non-active implantable devices



Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	AFX EndoVascular AAA System ,	9/30/2018	Endologix international holding B.V.	Tart Medical	FSN	https	
New	Gentle Thread PLGA Full Thread Interference Screw ,	9/25/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc	
New	Optetrak Logic CC Stem Extension, 22mm x 160mm	9/27/2018	Exactech	N/A	2	https://nc	
New	Peg Fully Threaded	9/25/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca	

Reusable devices

New	KURZ-PRECISE Cartilage Cutter	9/27/2018	Heinz Kurz GmbH	N/A	FSN	https	
-----	-------------------------------	-----------	-----------------	-----	-----	---------------------------	--

Single-use devices

New	Bipolar Electrode Catheter with shrouded pins ,	9/26/2018	Arrow International Inc	Gulf Medical Co.	2	https://nc	
New	CrystalClear Plus, RUSCH CARE CrystalClear (PVC) Tracheostomy Cannula (no Cuff) - Set, RUSCH CrystalClear (PVC) Tracheostomy Cannula (Cuffed / no Cuff)	9/30/2018	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https://nc.mdr.sfda.gov.sa/Sec	
New	Disposable Insulin Syringe 0.3mL	9/27/2018	ShinChang Medical Co., Ltd	N/A	2	https	
New	Durex Real Feel Polyisoprene Condoms	9/27/2018	Reckitt Benckiser Healthcare	Cigalah Group	2	https	
New	Embolectomy Catheters ,	9/30/2018	Dispomedica	N/A	FSN	https	
# New	Honeywell Laser Aid Disposable Eyepatches	9/26/2018	Medline Industries Inc....	Ikar Establishment	FSN	Attac	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Multiple Products ,	9/25/2018	Edwards Lifesciences	Health Care Supply Co. (2	A/Cal	
New	PICC Tray, Art-Line Surgery Pack-LF, Laparoscopy CDS, Cardiac Insulation Pad and LASER CDS	9/25/2018	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	2	https://ncmdr.sfda	
# New	PosiFlush Heparin Lock Flush Syringes and Prefilled Normal Saline Syringes	9/27/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	Attached	
# New	Single-Use Colpo-Pneumo Occluders	9/27/2018	Cooper Surgical, Inc.	Cure Development International Ltd	FSN	Attac	

* 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.