



**SBED Weekly Update** 07-Aug-17

Dear,  
SBED team is pleased to inform you that **27** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 8/1/2017 to 8/3/2017  
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
-----------	---------------	-----------	--------------	------------	-------	------

**Anaesthetic and respiratory devices**

Update	MONNAL T50	8/3/2017	ir Liquide Medical System	N/A	FSN	<a href="#">A/Ca\</a>
--------	------------	----------	---------------------------	-----	-----	-----------------------

**Diagnostic and therapeutic radiation devices**

New	Fujifilm Digital Mammography System ,	8/1/2017	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https://nc">https://nc</a>
-----	---------------------------------------	----------	--------------------------	---------------------------------	---	-------------------------------------

**Electro mechanical medical devices**



New	Accu-Chek Insight ,	8/3/2017	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	<a href="#">A/Ca\</a>
-----	---------------------	----------	------------------------	-------------------	-----	-----------------------

New	CareScape Patient Data Module (PDM) with software v2.6	8/1/2017	GE Healthcare	GE Healthcare	2	<a href="https://nc.mdr">https://nc.mdr</a>
-----	--	----------	---------------	---------------	---	---


New	Heater Unit HU 35	8/1/2017	aquet Cardiopulmonary A	I-Faisaliah Medical Syster	1	<a href="#">A/Ca\</a>
-----	-------------------	----------	-------------------------	----------------------------	---	-----------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	HF-Resection Electrodes	8/1/2017	Olympus	Salehiya Trading Est.	1	<a href="#">A/CaV</a>
# New	Model ED-530XT Duodenoscopes ,	8/1/2017	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	2	
# New	Video/Ultrasound Bronchoscopes and Video ,	8/1/2017	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	2	

### In vitro diagnostic devices

# New	Analyzer Software Used with FluoroType CDiff Systems	8/1/2017	Hain Lifescience GmbH	Bio Alternatives Establishment	2	
# New	BNP Reagent Kits used with ADVIA Centaur Systems	8/1/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
New	CAPI 3 IMMUNOTYPING, MINICAP IMMUNOTYPING and CAPILLARYS IMMUNOTYPING	8/3/2017	SEBIA	Dar Al-Zahrawi Medical Co. LLC	FSN	<a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a>
New	cobas 8000 core unit	8/1/2017	Roche Diagnostics Corp	MAAMOUN TAMER & Co	FSN	<a href="#">A/CaV</a>
New	Mueller Hinton E Agar (MHE)	8/1/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	<a href="https://nc">https://nc</a>



### Non-active implantable devices

New	Essure Permanent Birth Control System	8/1/2017	Bayer Healthcare LLC.	AL-KAMAL Import	2	<a href="https://nc">https://nc</a>
# Update	Instrumentation for E.T.O.I.L.E® system - E.T.O.I.L.E® extension table (leg holder)	8/2/2017	Amplitude GmbH	N/A	FSN	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	KickStand Post and Drill Guides	8/1/2017	Acumed LLC	N/A	2	
	New	NEO Non-Locking screw / NEOVIEW screw set	8/3/2017	In2Bones, SAS	N/A	FSN	<a href="https://nc">https://nc</a>
	New	Optimys stem lateral TAV 7 uncemented	8/3/2017	Mathys Ltd Bettlach	Isam Economic Co.	FSN	<a href="https://nc">https://nc</a>
	New	PulseRider® Aneurysm Neck Reconstruction Device	8/3/2017	Pulsar Vascular Inc.	N/A	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
#	New	Transpedicular Schanz Screws	8/1/2017	Synthes Inc	Isam Economic Co.	2	
#	Update	Vanguard Open Box Femoral Components	8/2/2017	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	

### Single-use devices

#	New	Affirm Lateral Arm Upright Biopsy Accessory Kits Used on Selenia Dimensions Mammography Systems	8/1/2017	Hologic Inc	Medical supplies & Services Co.Ltd Mediserv	2	
#	New	Certitude Delivery Systems ,	8/1/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	
#	New	MAX Vaginal Panels and UVE Specimen Collection Kits	8/1/2017	BD Biosciences	Becton Dickinson B.V.	2	
#	New	Sterile Admixtures Produced with Baxter 0.9% Sodium Chloride Injections in 250 mL VIAFLEX Plastic Containers	8/1/2017	SCA Pharmaceuticals	N/A	2	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Sterile Elastic Esmark Bandages	8/1/2017	Medline Industries Inc...	Ikar Establishment	2	
# Update	Various Tissu-Trans Products	8/2/2017	Shippert Medical Technologies Inc	N/A	2	

\* 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.