



SBED Weekly Update 14-Aug-18

Dear,  
SBED team is pleased to inform you that **30** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 8/6/2018 to 8/12/2018  
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
------	---------------	-----------	--------------	------------	-------	------	-----------------

**Active Implantable Devices**

#	New	Various Short-Term Hemodialysis Products	8/6/2018	Medcomp	Farabi Trading Establishment	FSN	<a href="#">Attac</a>	
---	-----	--	----------	---------	------------------------------	-----	-----------------------	--






**Anaesthetic and respiratory devices**

New	All lighting systems	8/8/2018	Dr. Mach GmbH & Co. KG	Nomas Trading	FSN	<a href="#">A/Ca\</a>	
New	Deltastream Heater-Cooler Unit	8/8/2018	Medos Medizintechnik AG..	Al Mofadaly Trading Est.	2	<a href="#">https</a>	
New	LipiVage system	8/8/2018	Genesis Biosystems Inc	ntific Equipment & Cosm	FSN	<a href="#">A/Ca\</a>	

**Assistive products for persons with disability**

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Dräger Ceiling Supply Unit; AGILA and Movita Lift Pendants	8/8/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	2	<a href="https://nc">https://nc</a>	
New	Pessary – Panpac Medical Corporation	8/8/2018	sellution medical GmbH	N/A	FSN	<a href="https">https</a>	

### Diagnostic and therapeutic radiation devices

#	New	Capnostream 20 and Capnostream 20p Bedside Patient Monitors	8/12/2018	Medtronic SA	Medtronic Saudi Arabia	2	<a href="Attached">Attached</a>	
	New	Enterprise Imaging for Radiology.	8/7/2018	AGFA Corp.	Gulf Medical Co.	FSN	<a href="https">https</a>	
	New	MOSAIQ Medical Oncology version 2.64 SP3 and higher	8/8/2018	Elekta Inc	Medical Regulations Gate	2	<a href="https://nc">https://nc</a>	
#	New	MX40 and MX4J Patient-Worn Monitor Patient Cable Connector Pins	8/12/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="Attached">Attached</a>	
#	New	MX40.. and MX4J Patient-Worn Monitors	8/12/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="Attached">Attached</a>	
	New	MyLab Alpha in combination with IH 6-18	8/8/2018	Esaote S.p.A.	Salehiya Trading Est.	2	<a href="https">https</a>	
	New	sterEOS image review workstation	8/7/2018	EOS Imaging	Bio Standards	FSN	<a href="https">https</a>	
#	Update	Various CT and PET Systems	8/6/2018	GE Healthcare	GE Healthcare	2	<a href="Attached">Attached</a>	
#	New	XLTEK EMU40EX EEG Headboxes	8/12/2018	Natus Medical Inc.	Saudi Health Services Co. Ltd.	2	<a href="Attached">Attached</a>	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Ysio and Ysio MAX systems and Multix Fusion Analog , Multix Fusion Digital Portable , Multix Fusion Digital Integrated and Multix Fusion Digital Wireless	8/7/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://nc.mdr.sfd.gov.sa/Se">https://nc.mdr.sfd.gov.sa/Se</a>	


### Electro mechanical medical devices

New	AMIA Automated PD Cyclor	8/7/2018	Baxter Corp Canada	Baxter AG	2	<a href="https://">https</a>	
-----	--------------------------	----------	--------------------	-----------	---	------------------------------	--

New	Think Surgical Cutter	8/8/2018	Think Surgical, Inc.	N/A	2	<a href="A/Ca">A/Ca</a>	
-----	-----------------------	----------	----------------------	-----	---	-------------------------	--


### In vitro diagnostic devices

#	New	Gibco RPMI 1640 Medium Reagents	8/12/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	<a href="Attac">Attac</a>		
---	-----	---------------------------------	-----------	-------------------------------	------------------------------------	---	---------------------------	--	---

#	New	Level 1 Custom Liquid Immunoassay Controls	8/12/2018	Randox Laboratories Ltd.	Bio Standards	2	<a href="Attac">Attac</a>		
---	-----	--	-----------	--------------------------	---------------	---	---------------------------	--	---

New	PP2030 Mannitol Salt Agar Plates.	8/8/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	<a href="https://">https</a>	
-----	-----------------------------------	----------	-------------------------------	------------------------------------	---	------------------------------	--

### Non-active implantable devices

#	New	Cellular- and Tissue-Based Products	8/12/2018	Aesculap	Gulf Medical Co.	2	<a href="Attac">Attac</a>		
---	-----	-------------------------------------	-----------	----------	------------------	---	---------------------------	--	---

New	Ennovate Rod Persuader	8/8/2018	Aesculap	Gulf Medical Co.	FSN	<a href="A/Ca">A/Ca</a>	
-----	------------------------	----------	----------	------------------	-----	-------------------------	--

New	Instrument trays used to store Altivate Small Shell Trials	8/7/2018	Encore Medical, Lp	AL EWAN MEDICAL COMPANY	2	<a href="https://nc">https://nc</a>	
-----	--	----------	--------------------	-------------------------	---	-------------------------------------	--

New	Modera Modular Pedicle Screw System	8/7/2018	New Era Orthopaedics, LLc	N/A	2	<a href="https://">https</a>	
-----	-------------------------------------	----------	---------------------------	-----	---	------------------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Sterile cannulated screws, Cannulated Screw 7.5	8/8/2018	aap Implantate AG.	Cure Development International Ltd	FSN	<a href="https">https</a>	

### Ophthalmic and optical devices

New	Uretero-Renoscope, Nephroscope	8/8/2018	Scholly Fiberoptic GMBH	Medical regulations gate	FSN	<a href="https">https</a>	
-----	--------------------------------	----------	-------------------------	--------------------------	-----	---------------------------	--

### Single-use devices

# New	Covidien Kerlix AMD, Kerlix, and Dermacea Bandage and Gauze Rolls	8/12/2018	Covidien LLC...	Medtronic Saudi Arabia	2	<a href="#">Attached</a>	
-------	---	-----------	-----------------	------------------------	---	--------------------------	--

New	DUREX Love Collection, DUREX Natural Feeling and DUREX Natural Feeling Easy Glide	8/8/2018	Reckitt Benckiser Healthcare	Cigalah Group	FSN	<a href="https://nc.mdr">https://nc.mdr</a>	
-----	---	----------	------------------------------	---------------	-----	---	--

# New	Prep Kits Containing BD Prefilled Normal Saline Syringes	8/12/2018	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">Attached</a>	
-------	--	-----------	--------------	------------------------	---	--------------------------	--

\* 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.