



## SBED Weekly Update

17-Apr-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 4/9/2018 to 4/15/2018  
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

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

**Active Implantable Devices**

New	HeartMate 3 Left Ventricular Assist System.	4/9/2018	Abbott Cardiovascular and Neuromodulation	Arabian Trade House Est.	FSN	<a href="#">https</a>
-----	---	----------	---	--------------------------	-----	-----------------------

**Anaesthetic and respiratory devices**

New	fabian Therapy evolution	4/9/2018	utronic Medical Systems A	Salehiya Trading Est.	FSN	<a href="#">A/Ca\</a>
-----	--------------------------	----------	---------------------------	-----------------------	-----	-----------------------


#	New	Hudson RCI One-Way Valves with Capped Monitoring Port	4/9/2018	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	1	
---	-----	---	----------	------------------	-------------------------------------	---	--

New	Oxygen Mask for adult, high concentration, non-rebreather/AsidBonz	4/11/2018	First Global Enterprises Limited	N/A	FSN	<a href="#">https://nc</a>
-----	--	-----------	----------------------------------	-----	-----	----------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Venner PneuX P.Y Endotracheal tube (Non-MRI)	4/11/2018	Venner Medical	N/A	FSN	<a href="https://nc">https://nc</a>

### Assistive products for persons with disability

New	First aid/emergency kits containing Honeywell eyewash	4/15/2018	Certified Safety Mfg Inc..	HEBA Fire & Safety Equip	2	<a href="https://nc">https://nc</a>
-----	---	-----------	----------------------------	--------------------------	---	-------------------------------------

#	New	WheelDrive Wheelchair Powered Assist Systems	4/9/2018	Sunrise Medical	Al-Enayah Company	2	
---	-----	--	----------	-----------------	-------------------	---	---

### Dental devices

New	InterActive Healing Collar	4/11/2018	Direct Sybron Manufactu	Abdullah Alzoman Est. fo	FSN	<a href="A/Ca">A/Ca</a>
-----	----------------------------	-----------	-------------------------	--------------------------	-----	-------------------------

### Diagnostic and therapeutic radiation devices

New	HomeSafe AutoAlert Pendant, AAHB, or AutoAlert Fall Detector	4/9/2018	Lifeline Systems, Incorporated	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc">https://nc</a>
-----	--	----------	--------------------------------	--------------------------------------	---	-------------------------------------

New	Intellivue X3	4/9/2018	Philips Burton	s Healthcare Saudi Arabi	2	<a href="A/Ca">A/Ca</a>
-----	---------------	----------	----------------	--------------------------	---	-------------------------

New	Intuition and Precision	4/9/2018	ARCOMA AB	N/A	FSN	<a href="A/Ca">A/Ca</a>
-----	-------------------------	----------	-----------	-----	-----	-------------------------

New	Rapid2 Therapy System	4/15/2018	e Magstim Company Limit	Attieh Medico Ltd.	2	<a href="A/Ca">A/Ca</a>
-----	-----------------------	-----------	-------------------------	--------------------	---	-------------------------

### Electro mechanical medical devices

New	Jaundice Meter JM-103 and JM-105 Out of Range Indication	4/15/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	<a href="https://nc">https://nc</a>
-----	--	-----------	-----------------------------	-------------------------	-----	-------------------------------------

New	Maquet VOLISTA StandOP Surgical Light	4/12/2018	Getinge Disinfection AB	Gulf Medical Co.	2	<a href="https">https</a>
-----	---------------------------------------	-----------	-------------------------	------------------	---	---------------------------

New	Multiple Introducers and Catheters	4/12/2018	Arrow International Inc	Gulf Medical Co.	2	<a href="https">https</a>
-----	------------------------------------	-----------	-------------------------	------------------	---	---------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Refractor Suspension Arm (P/N: 525004, 05 and 525006, 07)	4/11/2018	Reliance Medical Products.	Al Amin Medical Instruments Co. Ltd.	2	<a href="https://nc">https://nc</a>

#	New	Sternal Valve Retractors with Atrial and Aortic Attachments	4/9/2018	Genesee BIOMEDICAL, INC.	N/A	2	
---	-----	---	----------	--------------------------	-----	---	--

New	Volumed $\mu$ VP7000	4/9/2018	Arcomed AG	I-Faisaliah Medical System	FSN	<a href="A/Ca">A/Ca</a>
-----	----------------------	----------	------------	----------------------------	-----	-------------------------

### In vitro diagnostic devices

New	ADVIA Chemistry Systems Urea Nitrogen (UN)	4/11/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https">https</a>
-----	--	-----------	-------------------------------------	----------------------------	-----	---------------------------

New	Alere Afinion 2 Analyzer	4/9/2018	Alere.	Waleed Al-Madani Est.	FSN	<a href="A/Ca">A/Ca</a>
-----	--------------------------	----------	--------	-----------------------	-----	-------------------------

New	BD Vacutainer Citrate Plus Blood Collection Tubes	4/11/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	<a href="https://nc">https://nc</a>
-----	---	-----------	-----------------------------	-----------------------	-----	-------------------------------------

New	cobas MPX test, CE-IVD kit lots	4/15/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https">https</a>
-----	---------------------------------	-----------	------------------------	---------------------------------	---	---------------------------

New	FilmArray Blood Culture Identification (BCID) Panel	4/9/2018	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https">https</a>
-----	---	----------	-------------------------	-----------------------------------	-----	---------------------------

New	ImmunoCAP Allergen c6, Amoxicilloyl	4/9/2018	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https">https</a>
-----	-------------------------------------	----------	------------	----------------------------	---	---------------------------

New	LISS/Coombs, Coombs Anti-IgG, DiaScreen, LISS/Coombs + Enzyme test, DiaClon Type + Screen	4/9/2018	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
-----	---	----------	--------------	----------------------------	-----	---


Update	M-30D Diluent used with BC-3200 and BC-3600 Auto Hematology Analyzers ,	4/11/2018	Shenzhen Mindray	Salehiya Trading Est.	2	<a href="https://nc.mdr">https://nc.mdr</a>
--------	---	-----------	------------------	-----------------------	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Syva Emit II Plus 6-Acetylmorphine assay	4/11/2018	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
New	VIASURE Flu A, Flu B and RSV Real Time PCR Detection Kit to be used by BD MAX	4/11/2018	BD Diagnostic Systems	Becton Dickinson B.V.	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
New	VIDAS 3	4/9/2018	bioMerieux Inc	el Medical & Trading Co.	2	<a href="A/Ca">A/Ca</a>

### Medical software

#	New	Select Versions of Uri System Software	4/9/2018	Mast Group Ltd.	Al Nahir Trading Co	2	
---	-----	--	----------	-----------------	---------------------	---	---

### Non-active implantable devices

#	New	38 mm Offset Segmental System Proximal Femoral Components	4/9/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	
---	-----	---	----------	---------------------	-------------------	---	---

New	DRAD SelfTapping Locking Screw	4/9/2018	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc.mdr">https://nc.mdr</a>
-----	--------------------------------	----------	--------------------	--------------------	---	---

New	DynaMesh PR2 soft 2B , DynaMesh PR4 soft 2B	4/11/2018	FEG Textiltechnik Forschungs-und	Dome Medical Co	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
-----	---	-----------	----------------------------------	-----------------	-----	---

New	MUTARS HD Coupling C-O-M	4/11/2018	Implantcast	AlMafsal Medical Company	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
-----	--------------------------	-----------	-------------	--------------------------	-----	---

New	ORTHOFIX, Connector System, SMALL and LARGE SET SCREW	4/15/2018	Orthofix	Arabian Health Care Supply Co. (AHCSC)	2	<a href="https://nc.mdr">https://nc.mdr</a>
-----	---	-----------	----------	--	---	---

New	Valor Nail	4/11/2018	ght Medical Technology ,I	Health Care Supply Co. (	FSN	<a href="A/Ca">A/Ca</a>
-----	------------	-----------	---------------------------	--------------------------	-----	-------------------------

### Ophthalmic and optical devices


New	AUTO REF/KERATOMETER ARK1s	4/12/2018	Nidek Inc.	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
-----	----------------------------	-----------	------------	-----	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

### Reusable devices

	New	Cardiovascular Procedure Kits, Tubing Pack	4/9/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https">https</a>
--	-----	--	----------	---	----------------------------	---	---------------------------


### Single-use devices

#	New	Angio-Seal Evolution Vascular Closure Devices	4/15/2018	Terumo Medical Corp..	Al-Jeel Medical & Trading Co. LTD	2		
---	-----	---	-----------	-----------------------	-----------------------------------	---	--	---

	New	ENDOPATH XCEL Trocars with OPTIVIEW Technology	4/9/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	FSN	<a href="https://nc">https://nc</a>
--	-----	--	----------	--------------	--	-----	-------------------------------------


	Update	MindFrame Capture LP Devices	4/11/2018	Medtronic SA	Medtronic Saudi Arabia	1	<a href="https">https</a>
--	--------	------------------------------	-----------	--------------	------------------------	---	---------------------------

	New	PDS Plus Antibacterial monofilament syntheticabsorbable sutures	4/12/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	2	<a href="https://nc">https://nc</a> <a href="mdr">mdr.</a>
--	-----	---	-----------	--------------	--	---	---

#	New	Shadow Holdings Remedy Essentials Foaming Cleanser	4/9/2018	Medline Industries Inc....	Ikar Establishment	2		
---	-----	--	----------	----------------------------	--------------------	---	--	---

	New	Smallbore Ext Set w/MicroClave, Clave TConnector, Clamp, Rotating Luer	4/12/2018	ICU Medical, Inc	AL-KAMAL Import	2	<a href="https://nc">https://nc</a> <a href="mdr">mdr.</a>
--	-----	--	-----------	------------------	-----------------	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

- \* 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.