



**SBED Weekly Update** 24-Apr-18

Dear,  
SBED team is pleased to inform you that **31** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 4/16/2018 to 4/22/2018  
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
-----------	---------------	-----------	--------------	------------	-------	------

**Anaesthetic and respiratory devices**

#	New	Halyard Health Closed Suction Kits with Flex Connector	4/16/2018	Halyard Health Co.	Arabian Health Care Supply Co. (AHCSC)	2	<a href="#">Attac hed</a>
	Update	Halyard Health Closed Suction Kits with Flex Connector	4/19/2018	Halyard Health Co.	Arabian Health Care Supply Co. (AHCSC)	2	<a href="https://nc">https://nc</a>

**Assistive products for persons with disability**

#	New	Entroy Pool Lifters	4/16/2018	rjo Hospital Equipment A	I-Faisaliah Medical Syster	2	<a href="#">A/Ca\</a>
	New	Milford Smartbase	4/19/2018	Autochair	N/A	2	<a href="#">A/Ca\</a>

**Complementary therapy devices**

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Phantom Fiber Biofiber Sutures	4/16/2018	Tornier Inc	N/A	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>

### Diagnostic and therapeutic radiation devices

New	Nuclear, Magnetic Resonance Imaging	4/19/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
New	Philips Ingenuity Core (728321)	4/19/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>

### Electro mechanical medical devices

New	Battery Performance Alert and Cybersecurity Firmware Updates for Certain ICD & CRT-D Devices	4/22/2018	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
-----	--	-----------	----------------------	-----------------------------------	-----	---



New	Belzer UW & Waters IGL Cold Storage Solution	4/18/2018	Preservation Solutions, Inc	N/A	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
-----	--	-----------	-----------------------------	-----	---	---

New	Classic Series Reusable Active Cord designed to be used with Gyrus ACMI FOCUS 640, Bovie and other general purpose monopolar electro-surgical generators	4/22/2018	Gyrus ACMI	Salehiya Trading Est.	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
-----	--	-----------	------------	-----------------------	---	---


#	New	Covidien EEA Hemorrhoid and Prolapse Stapler Sets with DST Series Technology	4/16/2018	Medtronic SA	Medtronic Saudi Arabia	1	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
---	-----	--	-----------	--------------	------------------------	---	---

New	Infinity Acute Care System (IACS) Monitoring Solution	4/18/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
-----	---	-----------	-----------------------------	-------------------------	---	---

New	Liberty Select Cyclor	4/16/2018	Fresenius Medical Care.	Fresenius Medical Care Gm	2	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
-----	-----------------------	-----------	-------------------------	---------------------------	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Microflex Spare Part Drives for T2100 Treadmills	4/16/2018	GE Healthcare	GE Healthcare	2	<a href="#">Attac hed</a> 
# New	SIGMA Spectrum V6 Platform Infusion Pumps with Master Drug Library ,	4/18/2018	Baxter Healthcare	Baxter AG	2	<a href="#">Attac hed</a> 
New	Sonopet Ultrasonic Products ,	4/22/2018	Stryker Instruments ( Ultrasonic Sys )	Arabian Medical Express Services (	2	<a href="https">https</a>


### In vitro diagnostic devices

New	Alinity i HBsAg Calibrators	4/22/2018	Abbott	ppplies & Services Co.Ltd	FSN	<a href="#">A/CaV</a>
New	Atellica COAG 360...	4/16/2018	s Healthcare Diagnostics F	AL-KAMAL Import	2	<a href="#">A/CaV</a>
New	BD Vacutainer EDTA tubes, BD Vacutainer Lithium Heparin tubes	4/16/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	<a href="https://nc">https://nc</a>
New	EliA Intrinsic Factor Well .	4/19/2018	Phadia Ltd	ULREHMAN AL GOSAIBI	2	<a href="#">A/CaV</a>
New	Mueller Hinton	4/16/2018	Bio-Rad Laboratories Inc	el Medical & Trading Co.	2	<a href="#">A/CaV</a>
New	SALSA MLPA Probemix P060 SMA	4/16/2018	MRC-Holland	N/A	FSN	<a href="https">https</a>
# New	Sample Diluents used with Dimension Vista Systems	4/16/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	<a href="#">Attac hed</a> 

### Non-active implantable devices


New	Implant, Ext. Hex, tapered 12o CoAxis	4/18/2018	Southern Implants, Inc	N/A	2	<a href="https">https</a>
-----	---------------------------------------	-----------	------------------------	-----	---	---------------------------

### Reusable devices

# Update	Hypothermia Caps, Mittens and Slippers	4/16/2018	Southwest Technologies	N/A	2	
----------	--	-----------	------------------------	-----	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Surgical PENIS CLAMP	4/22/2018	Aesculap	Gulf Medical Co.	FSN	<a href="#">A/Cal</a>

### Single-use devices

#	New	Vacutainer Plus Plastic Citrate Blood Collection Tubes	4/18/2018	BD Biosciences	Becton Dickinson B.V.	2	<a href="#">Attac hed</a> 
	New	Alaris SMARTSITE ADD-ON BAG ACCESS DEVICE	4/16/2018	Becton, Dickinson And Company	Medical Regulations Gate	2	<a href="#">https</a>
	New	IntraClude Intra-aortic Occlusion Device ,	4/19/2018	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	1	<a href="#">https</a>
	New	Liquid Acid Concentrate for Haemodialysis-HDA08	4/22/2018	Alrazi Pharma Industries	Alrazi Pharma Industries	FSN	<a href="#">https</a>
	Update	Thoracentesis/paracentesis kit, Illinois needle aspiration, Jamshidi needle bone marrow	4/19/2018	CareFusion Alaris A BD Co	Becton Dickinson B.V.	2	<a href="#">https://ncmdr.</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.