



**SBED Weekly Update** 03-Oct-17

Dear,  
SBED team is pleased to inform you that **32** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 9/25/2017 to 9/28/2017  
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
-----------	---------------	-----------	--------------	------------	-------	------

**Active Implantable Devices**

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	Infinity Neuromodulation Implantable Pulse Generators	9/25/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	

**Assistive products for persons with disability**

New	Alevo Alu	9/28/2017	Medizin- und Rehabilitat	N/A	FSN	<a href="#">A/Ca\</a>
-----	-----------	-----------	--------------------------	-----	-----	-----------------------

**Diagnostic and therapeutic radiation devices**

Update	Brilliance 64/ Ingenuity CT / Ingenuity Core / Ingenuity Core128	9/26/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="https://nc">https://nc</a>
New	Robot Imager, Gantry Imager.	9/28/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https">https</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	SureSigns VSi, SureSigns VS2+ monitors	9/26/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="https">https</a>
# Update	Wireless Foot Switch utilised on Artis systems	9/25/2017	SIEMENS	Siemens Medical Solutions	2	
New	ZEISS INTRABEAM PRS 500	9/28/2017	Carl Zeiss Meditec Inc	Gulf Medical Co.	FSN	<a href="https">https</a>

### Electro mechanical medical devices

# New	8 cm Angled Attachments	9/25/2017	The Anspach Effort, Inc.	Al-Nozha Medical Est	2	
New	Covidien GastriSail Gastric Positioning System	9/26/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https">https</a>
New	EA010, VOYANT ESG 1/BX	9/28/2017	Applied Medical Resource	Dawha Medical	FSN	<a href="A/Cal">A/Cal</a>
# New	T Series Operating Tables	9/25/2017	Eschmann Equipment	Salehiya Trading Est.	2	

### In vitro diagnostic devices

# New	AU Lyophilized Chemistry Level 1 Calibrators	9/25/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	
# New	Certain IVD Downstream Applications Tested Using GXT NA Extraction Kits	9/25/2017	Hain Lifescience GmbH	Bio Alternatives Establishment	2	
New	Lipid Control - Level 3	9/28/2017	Randox Laboratories Ltd.	Bio Standards	FSN	<a href="A/Cal">A/Cal</a>
New	NK034.S - Human Alpha 1 Antitrypsin Kit for on the SPAPLUS	9/28/2017	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc">https://nc</a>
New	oneHbA1c IS, Super ID HbA1c	9/28/2017	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	<a href="https">https</a>
New	ORG 248 Alegria anti-MCV	9/28/2017	ORGENTEC	REDWAN MEDICAL SERVICES	FSN	<a href="https">https</a>


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	ORTHO Vision & Vision Max Analyzer	9/28/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	<a href="https://nc">https://nc</a>
New	Remel Vibrio Cholerae Ogawa agglutinating serum	9/28/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>
New	UIBC FS 1 1921	9/28/2017	ys Diagnostic Systems Gn	Ghuyum Scientific Tradir	FSN	<a href="A/Ca">A/Ca</a>

### Non-active implantable devices


	New	aap Drill Guide LOQTEQ VA with scale up to L 28, drill diam. 2.0, 0	9/28/2017	aap Implantate AG	Saudi Import Co. Banaja	FSN	<a href="https://nc">https://nc</a>
#	New	DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Prostheses	9/25/2017	Synthes GmbH	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https://nc.mdr">https://nc.mdr</a>
#	New	Heli-FX Guide Devices	9/25/2017	Medtronic SA	Medtronic Saudi Arabia	2	
#	New	Magic3, HydroSil Gripper, and Personal Intermittent Catheters	9/25/2017	C R Bard Inc	C.R. BARD Saudi Arabia	2	
	New	META-TAN 10MM X 34CM LEFT	9/28/2017	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="https">https</a>
	New	META-TAN 10MM X 38CM RIGHT	9/28/2017	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="https">https</a>
#	New	The Second Assistant Disposable Knee Positioners	9/25/2017	Zimmer, INC....	Medical Regulations Gate	2	


### Reusable devices

#	New	da Vinci Xi EndoWrist Stapler 45 Instruments	9/25/2017	Intuitive Surgical Inc	Gulf Medical Co.	2	
---	-----	--	-----------	------------------------	------------------	---	--

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Medtronic Covidien Endo GIA AutoSuture Universal Articulating Loading Units	9/25/2017	Medtronic SA	Medtronic Saudi Arabia	2	

### Single-use devices

#	New	Blockaid Cut-Resistant Surgical Glove Liners	9/25/2017	Zimmer, INC....	Medical Regulations Gate	2	
---	-----	--	-----------	-----------------	--------------------------	---	---

#	New	Metalline Tracheo Dressings	9/25/2017	Lohmann & Rauscher International	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	
---	-----	-----------------------------	-----------	----------------------------------	-------------------------------------	---	---

New	Neuray Neurosurgical Patties and Strips and Meroceel Neurosurgical Pattie and Packing	9/26/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a data-bbox="1453 672 1518 777" href="https://ncmdr.">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.