



**SBED Weekly Update** 13-Jun-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 6/5/2017 to 6/11/2017  
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**

New	Pall "Ultipor" 100 Breathing System Filter	6/11/2017	Pall International SARL	Arabian Trade House Est.	FSN	<a href="#">https</a>
-----	--	-----------	-------------------------	--------------------------	-----	-----------------------

**Dental devices**

New	BEGO Semados S. 3,25 L13	6/11/2017	BEGO Implant Systems GmbH & Co. KG	ABIAT AL-TIBB CO.	FSN	<a href="#">https</a>
-----	--------------------------	-----------	------------------------------------	-------------------	-----	-----------------------

**Diagnostic and therapeutic radiation devices**

New	Berchtold Chromophare	6/7/2017	Stryker Communications	I-Faisaliah Medical Syster	2	<a href="#">A/Ca\</a>
-----	-----------------------	----------	------------------------	----------------------------	---	-----------------------

New	Infant Radiant Warmer.	6/11/2017	GE Healthcare	GE Healthcare	2	<a href="#">A/Ca\</a>
-----	------------------------	-----------	---------------	---------------	---	-----------------------

New	Infinity Acute Care System (IACS).	6/11/2017	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	<a href="#">https</a>
-----	------------------------------------	-----------	-----------------------------	-------------------------	-----	-----------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	MEVASIM, MEVASIM S, SIMVIEW 3000 and SIMVIEW NT	6/11/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://nc">https://nc</a>

New	Sesamoid Plasty	6/5/2017	Orthosoft, Inc	N/A	2	<a href="A/Ca">A/Ca</a>
-----	-----------------	----------	----------------	-----	---	-------------------------

### Electro mechanical medical devices

New	G-EO System	6/8/2017	Reha Technology AG	N/A	FSN	<a href="A/Ca">A/Ca</a>
-----	-------------	----------	--------------------	-----	-----	-------------------------

New	Nexstim, NBS System	6/11/2017	Nexstim OY	in Medical Instruments C	2	<a href="A/Ca">A/Ca</a>
-----	---------------------	-----------	------------	--------------------------	---	-------------------------

New	Transfer Set	6/5/2017	Baxter Corp Canada	Baxter AG	2	<a href="A/Ca">A/Ca</a>
-----	--------------	----------	--------------------	-----------	---	-------------------------

### In vitro diagnostic devices

New	DxH 500 Haematology Analyser	6/7/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	<a href="https">https</a>
-----	------------------------------	----------	-----------------	-----------------------------------	---	---------------------------

New	Estrogen Receptor (EP1)	6/5/2017	Cell Marque Corporation	el Medical & Trading Co.	2	<a href="A/Ca">A/Ca</a>
-----	-------------------------	----------	-------------------------	--------------------------	---	-------------------------

New	PrepPlus & PrepPlus 2	6/7/2017	Beckman Coulter	el Medical & Trading Co.	FSN	<a href="A/Ca">A/Ca</a>
-----	-----------------------	----------	-----------------	--------------------------	-----	-------------------------

New	PROT 1 CAL and PROT 1 CON when used with Dimension Vista CER Flex Reagent Cartridge	6/5/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https://nc.mdr">https://nc.mdr</a>
-----	---	----------	-------------------------------------	----------------------------	---	---

New	RAPIDLab 348 / RAPIDLab 348EX Gas cartridge pack	6/8/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	<a href="https://nc">https://nc</a>
-----	--	----------	--------------------------------	---	-----	-------------------------------------

### Laboratory equipment

New	Cardinal, Digital Bariatric Scale	6/5/2017	Cardinal scale manufacturing company	Regulatory Standards	2	<a href="https">https</a>
-----	-----------------------------------	----------	--------------------------------------	----------------------	---	---------------------------

New	Draco Enzymatic DeepCleaning Pad with Enzymatic Detergent	6/5/2017	Madison Polymeric Engineering	N/A	2	<a href="https://nc">https://nc</a>
-----	---	----------	-------------------------------	-----	---	-------------------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	MULTIGENT Creatinine (Enzymatic)	6/11/2017	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>

### Non-active implantable devices

New	611 Ankle Fusion Nail Drill	6/11/2017	Tornier Inc	N/A	FSN	<a href="A/Ca">A/Ca</a>
New	DePuy Synthes orthopedic instruments	6/11/2017	Depuy Orthopaedics, Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https">https</a>
New	Response BandLoc 5.5/6.0 Tensioner Instrument	6/11/2017	OrthoPediatics Corp	ProMedEx	2	<a href="https://nc">https://nc</a>
New	Shuntassistant	6/11/2017	Aesculap	Gulf Medical Co.	FSN	<a href="A/Ca">A/Ca</a>

### Ophthalmic and optical devices

New	Alcon LuxOR LX3 Microscope Floor Stand	6/7/2017	Alcon LenSx, Inc	Al Amin Medical Instruments Co. Ltd.	FSN	<a href="https">https</a>
New	Tango Reflex	6/7/2017	Ellex Medical Pty Ltd	Saad Al Bashir	2	<a href="A/Ca">A/Ca</a>


### Reusable devices

Update	Brennen Skin Graft Mesher	6/11/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	<a href="https">https</a>
New	Various Terumo Introducer Kits	6/7/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https">https</a>

### Single-use devices

New	AXS Universal Aspiration Tubing	6/11/2017	Medela AG.	salehiya Trading Est.	FSN	<a href="https">https</a>
New	Laser Guide, Endotherapy	6/6/2017	Tobrix BV.	Arabian Trade House Est.	1	<a href="A/Ca">A/Ca</a>
New	IntelliCuff Standalone	6/8/2017	Hamilton Medical Inc	Taleiamedical	FSN	<a href="A/Ca">A/Ca</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	SBK Cut Biopsy Needle / MS-cut	6/11/2017	Angiomed GmbH & Co. Medizintechnik KG.	C.R. BARD Saudi Arabia	FSN	<a href="https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx">https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx</a>
New	VueOptic Visualisation Source & Flexor Vue Deflecting Endoscopic System	6/7/2017	Cook Medical	NAFA Medical	2	<a href="https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx">https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx</a>
New	Zurpaz Steerable Sheath 8.5F Asymmetric and Symmetric Curve	6/11/2017	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx">https://ncmdr.gov.sa/Secure/CA/CaCompositeListing.aspx</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.sfd.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.