



**SBED Weekly Update** 06-Feb-18

Dear,  
SBED team is pleased to inform you that **33** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 1/29/2018 to 2/1/2018  
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
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**Anaesthetic and respiratory devices**

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	9100c and Aelite Anesthesia Systems	1/29/2018	GE Healthcare	GE Healthcare	2	

**Dental devices**

	New	Elements Obturation Unit	1/29/2018	SybronEndo Corporation	MAAMOUN TAMER & C	2	<a href="#">A/Ca\</a>
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**Diagnostic and therapeutic radiation devices**

	New	Metrotom 800	1/29/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	<a href="#">A/Ca\</a>
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	New	Syngo Imaging.	1/29/2018	Siemens Medical Solutions	Siemens Medical Solution	2	<a href="#">A/Ca\</a>
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	Update	TAYLOR SPATIAL FRAME WEBSITE SOFTWARE	1/29/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="#">https</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	UROS AUTOMATED URINE OUPUT AND TEMPERATURE MONITOR	2/1/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	<a href="https://nc">https://nc</a>

### Electro mechanical medical devices

New	Dornier Gemini	2/1/2018	Dornier MedTech GmbH	ATTIEH MEDICO LTD	FSN	<a href="A/CaV">A/CaV</a>
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# Update	Uretero-Reno Fiberscopes	1/31/2018	Olympus	Salehiya Trading Est.	2	<a href="ttache">ttache</a> 
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### In vitro diagnostic devices

Update	BD Phoenix Gram Negative Panels containing Colistin	2/1/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	<a href="https://nc">https://nc</a>
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New	Cortisol Saliva Luminescence Immunoassay	1/30/2018	Tecan Sales Austria GmbH	Samir Photographic Supplies Co. Ltd.	FSN	<a href="https://nc">https://nc</a>
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New	LABGEO HC10	1/30/2018	MSUNG MEDISON CO.,LTD	El Seif Company	FSN	<a href="A/CaV">A/CaV</a>
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# Update	Panther and Panther Fusion Systems with 19-in monitor	1/29/2018	HOLOGIC NV	Al-Jeel Medical & Trading Co. LTD	2	
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New	Triage Drugs of Abuse Plus TCA 25 Test Kit	2/1/2018	Alere	Techno-Orbits Establishment	2	<a href="https">https</a>
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Update	Vacurette Minicollect Complete 1mL Sodium Citrate 3.2%.	1/30/2018	Greiner Bio-One Inc	Al Hammad Medical Services	2	<a href="https://nc">https://nc</a>
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# New	Xpert HIV-1 Viral Load Assays ,	1/29/2018	Cepheid	ABDULLA FOUAD HOLDING COMPANY	2	
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### Non-active implantable devices

Update	Affixus Hip Fracture Nail ,	1/31/2018	Zimmer inc	im M. Al-Mana & Bros. C	2	<a href="A/CaV">A/CaV</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Anchor Drive for Cardioband System	1/30/2018	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	FSN	<a href="https://nc">https://nc</a>
New	Equinoxe Cage, Glenoid, Alpha, Small and Medium	2/1/2018	Exactech	N/A	2	<a href="https://nc">https://nc</a>
New	EVOS FLEX PLATE	1/29/2018	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc">A/CaV</a>
New	Gi Dynamics EndoBarrier Gastrointestinal Liner with Delivery System	1/30/2018	GI Dynamics Inc	Al-Nozha Medical Est	FSN	<a href="https://nc">https://nc</a>
New	Radial Osteotome Blade	1/29/2018	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc">A/CaV</a>
New	Revivent TC Ventricular Enhancement System	1/30/2018	BioVentrix, Inc.	N/A	FSN	<a href="https://nc">https://nc</a>
New	sinus-SuperFlex-635.	2/1/2018	Medizinische Instrument	Syts Trading Est.	FSN	<a href="https://nc">A/CaV</a>

### Reusable devices

New	Invia Motion Negative Pressure Wound Therapy (NPWT) system	2/1/2018	Medela AG.	salehiya Trading Est.	FSN	<a href="https://nc">https://nc</a>
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### Single-use devices


New	3M™ Bair Hugger™ Full Access Underbody Warming Blanket ,	1/31/2018	3M Health Care Ltd	3M company	FSN	<a href="https://nc">https://nc</a>
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#	New	DIANEAL PD4 CAPD Solution with 1.5% Dextrose and 2.5 meq/L Calcium (One Lot)	1/29/2018	Baxter Healthcare	Baxter AG	2	
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New	DOUBLE ROW FOOTPLATES, TL-HEX STERILE	2/1/2018	Orthofix	Arabian Health Care Supply Co. (AHCSC)	FSN	<a href="https://nc">https://nc</a>
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New	Fraizer suction handle	2/1/2018	GCMedica Enterprise Ltd	Faalya Advance Compar	2	<a href="https://nc">A/CaV</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# Update	Guider Softip XF Guide Catheters	1/30/2018	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	2	
# New	LAP-BAND AP Adjustable Gastric Banding Systems	1/30/2018	Apollo Endosurgery Inc.	Al-Nozha Medical Est	2	
Update	MARS Kit Gambro	1/29/2018	Gambro Lundia AB	Baxter AG	FSN	<a href="#">A/Ca\</a>
New	Tumark Q	1/29/2018	TEX Medical Technologies	nights Of Technology. Es	2	<a href="#">A/Ca\</a>
# New	Various Stryker Disposable Products ,	1/31/2018	Stryker Instruments	Al-Faisaliah Medical System	2	

- \* 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.