



## SBED Weekly Update

09-Jan-18

Dear,

SBED team is pleased to inform you that **34** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 1/1/2018 to 1/7/2018  
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	Distributor	Class	Link
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**Anaesthetic and respiratory devices**

New	BVM (Bag-Valve-Mask) Manual Resuscitation Systems	1/7/2018	Intersurgical Limited	Al Hammad Medical Services	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
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New	Spangenbezug C-SET, PE	1/7/2018	Udo Heisig GmbH	N/A	FSN	<a href="#">A/Ca\</a>
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**Diagnostic and therapeutic radiation devices**

New	IPS CaseDesigner	1/7/2018	Nobel Biocare Services AB	Medical Regulations Gate	FSN	<a href="#">A/Ca\</a>
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New	Monica IF24 Interface Systems	1/1/2018	GE Healthcare	GE Healthcare	FSN	<a href="https://nc">https://nc</a>
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New	SOMATOM GO.UP and SOMATOM go.Now.	1/1/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://nc">https://nc</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	syngo Workflow MLR..	1/7/2018	SIEMENS	iemens Medical Solution	FSN	<a href="#">A/Ca\</a>
New	TAYLOR SPATIAL FRAME WEBSITE SOFTWARE	1/1/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="https://nc">https://nc</a>

### Electro mechanical medical devices

New	CADD Legacy	1/7/2018	Smiths Medical ASD Inc..	CARE DRUG STORE COM	2	<a href="#">A/Ca\</a>
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### In vitro diagnostic devices

#	New	ADVIA Centaur CP, XP, and XPT Systems ,	1/7/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	<a href="#">Attac hed</a>	
	New	Atellica UAS 800 analyzer	1/3/2018	Siemens Healthcare Diagnostic	ABDULREHMAN AL GOSAIBI	FSN	<a href="#">A/Ca\</a>	
	New	Atellica UAS 800 analyzer.	1/7/2018	Siemens Healthcare Diagnostic	ABDULREHMAN AL GOSAIBI	FSN	<a href="#">A/Ca\</a>	
	New	BD Vacutainer Boric Acid Sodium Borate/Formate C&S Urine Tube	1/3/2018	BD Biosciences	Becton Dickinson B.V.	FSN	<a href="https://nc.mdr">https://nc.mdr.</a>	
	New	Hematoxylin II and Horseradish Peroxidase reagents	1/2/2018	Roche Diagnostics GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc.mdr">https://nc.mdr.</a>	
	New	ImmunoCAP Allergen c5, ImmunoCAP Allergen c6	1/1/2018	ThermoFisher.	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https://nc">https://nc</a>	
	New	VACUETTE FC MIX Tube	1/3/2018	Greiner Bio-One Inc	Hammad Medical Service	FSN	<a href="#">A/Ca\</a>	
	New	Xpert GBS	1/1/2018	Cepheid	A FOUAD HOLDING COM	FSN	<a href="#">A/Ca\</a>	

### Laboratory equipment

#	New	Specimen Gate Screening Center Systems	1/1/2018	Perkin Elmer Health Sciences, Inc	N/A	2	<a href="#">Attac hed</a>	
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### Non-active implantable devices

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	ACE Trochanteric Nail System Products ,	1/7/2018	Zimmer Inc.....	Isam Economic Co.	2	<a href="#">Attac hed</a> 
	New	Custom Implants with Minimally Invasive Grower (MIG) component	1/3/2018	Stanmore Implants Worldwide Ltd.	Zimmo Trading Establishment.	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
	New	IQ E.MOTION PS PRO SLEEVE F/BOX CUTTER M	1/1/2018	Aesculap	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
	New	Motiva Implants	1/3/2018	Establishment Labs S.A.	CO FOR MEDICAL EQUIPM	FSN	<a href="#">A/Ca\</a>
	New	OSS CEMENTED IM STEM , CER BIOLOXD OPTION HD , CER OPTION TYPE ,	1/1/2018	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
#	New	SIGMA HP Cemented Trochlea Implants	1/7/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia	2	<a href="#">Attac hed</a> 

### Ophthalmic and optical devices

	New	Laser Safety Glasses	1/7/2018	eder Martin GmbH & Co	I-Faisaliah Medical Syster	FSN	<a href="#">A/Ca\</a>
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### Single-use devices

	New	Agilis	1/1/2018	St. Jude Medical Inc	el Medical & Trading Co.	1	<a href="#">A/Ca\</a>
#	New	Arrow Various Catheterization Kits ,	1/1/2018	Arrow International Inc	Gulf Medical Co.	2	<a href="#">Attac hed</a> 
#	New	Band-Aid and Coach Sport Wraps ,	1/1/2018	Johnson & Johnson Medical GmbH	Johnson & Johnson Medical Saudi Arabia	2	<a href="#">Attac hed</a> 
	New	CF-5242 – Peritoneal Dialysis Catheter	1/1/2018	Merit Medical Systems Inc	Majal Care for Trading Est.	FSN	<a href="https://nc">https://nc</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	CORTRAK 2 Nasogastric/Nasointestina l Feeding Tube with Electromagnetic Transmitting Stylet with ANTI-IV Connector	1/1/2018	Halyard Health Co.	Arabian Health Care Supply Co. (AHCSC)	FSN	<a href="https://ncmdr.sfda.gov.sa/Se">https://ncmdr.sfda.gov.sa/Se</a>
New	DS Titanium Ligation- Clips	1/3/2018	Aesculap	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
# New	Guider Softip XF Guide Catheters	1/1/2018	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="#">Attac hed</a>
New	PICO70 Arterial Blood Sampler	1/1/2018	Radiometer America Inc	Salehiya Trading Est.	FSN	<a href="https://nc">https://nc</a>
New	SafetyCat PLUS / B.Braun wit Syringe	1/7/2018	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="https://nc">https://nc</a>
# New	Vado Steerable Sheaths	1/1/2018	Terumo BCT Inc	ULREHMAN AL GOSAIBI	2	<a href="#">ttache</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.