



**SBED Weekly Update** 13-Sep-17

Dear,

SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 9/4/2017 to 9/10/2017  
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
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### Active Implantable Devices

Update	Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura and Unify Quadra	9/4/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://ncmdr">https://ncmdr</a>
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### Anaesthetic and respiratory devices

#	New	MR-Conditional Cylinders	9/10/2017	Newmatic	N/A	2	<a href="#">ttache</a>
	New	SERVO-air..	9/6/2017	Maquet Critical Care AB	Gulf Medical Co.	FSN	<a href="#">A/Cal</a>
	Update	Unomedical Oxygen Masks,	9/7/2017	ConvaTec	Salehiya Trading Est.	2	<a href="#">https</a>

### Assistive products for persons with disability

	New	Iris Hi Lo Bed	9/9/2017	ride Mobility Products Ltd	alsandross international	2	<a href="#">A/Cal</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	JHI-303 Reserve Battery/Charger	9/7/2017	Jarvik Heart Inc	N/A	FSN	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
New	Permobil powered wheelchair C300, C350, C400, and C500 with seats Corpus II, Corpus II LR, Corpus KB and Base Only	9/6/2017	Permobil AB	N/A	FSN	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>

### Diagnostic and therapeutic radiation devices

New	Artis one system with DP Transceiver below	9/4/2017	Siemens Medical Solutions	Siemens Medical Solutions	2	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
New	Merge Unity software	9/9/2017	Merge Healthcare Corp.	N/A	2	<a href="https://ncmdr.sfda.gov.s">A/Ca</a>
New	Ultimax Digital Fluoroscopic XRay System	9/9/2017	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>

### Electro mechanical medical devices

#	New	AT-4000 Series Advanced Wire Tracer Kits	9/4/2017	Amprobe	N/A	2	<a href="https://ncmdr.sfda.gov.s">Attac</a>
	New	Bullfrog Micro-Infusion Device	9/6/2017	Mercator MedSystems, Inc.	N/A	FSN	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
	New	Graseby 3300 Pump and Graseby 3000 Series Accessories	9/9/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>

### In vitro diagnostic devices

	New	ABX PENTRA HbA1c WB Cal	9/7/2017	Horiba ABX SAS	Abdulrauf Ibrahim Batterjee & Bros.	FSN	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
	New	Epiclone Anti N BGR - Immunohaematology Reagent.	9/4/2017	Seqirus Pty Ltd	N/A	2	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>
	New	FLUROCELL PLT.	9/7/2017	Sysmex Europe GmbH.	MAAMOUN TAMER & C	FSN	<a href="https://ncmdr.sfda.gov.s">A/Ca</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
Update	Streptex Rapid Latex Agglutination Test.	9/6/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	<a href="https://nc">https</a>
New	TM0268 GC Sugar Set	9/9/2017	isher Scientific Microbiolo	d Abdul Jalil Al Fadhli & S	2	<a href="A/CaV">A/CaV</a>
New	VITROS Immunodiagnostic Products Signal Reagent	9/4/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	<a href="https://nc">https://nc</a>

### Non-active implantable devices

New	Essure Permanent Birth Control.	9/6/2017	Bayer Healthcare LLC.	AL-KAMAL Import	2	<a href="https">https</a>
New	Persona Tibial Plate Provisionals and Tibial Sizing Plates	9/6/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>
Update	Polarstem Cardan for 21000438	9/4/2017	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https">https</a>
Update	RIO THA System	9/4/2017	er Howmedica Osteonics	nmo Trading Establishme	2	<a href="A/CaV">A/CaV</a>
New	Turon Glenoid Reamer	9/4/2017	Encore Medical, Lp	Al Ewan Medical Compan	2	<a href="A/CaV">A/CaV</a>

### Single-use devices

#	New	AXS Offset Delivery Assist Catheters	9/4/2017	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https">https</a>
	Update	Bridge Occlusion Balloons.	9/7/2017	Spectranetics Corporation	Almarfa Medical	2	<a href="A/CaV">A/CaV</a>
	New	Ring Transjugular Intrahepatic Access Set	9/7/2017	Cook Inc,	NAFA Medical	FSN	<a href="https">https</a>
	New	Sterile Water, Saline and Eye Wash	9/7/2017	Smiths Medical International Limited	almarad medical Est.	FSN	<a href="https">https</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Vacutainer K2 EDTA 3.6 mg Blood Collection Tubes	9/4/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	<a href="#">Attached</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.