



**SBED Weekly Update** 30-Oct-17

Dear,

SBED team is pleased to inform you that **40** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 10/23/2017 to 10/29/2017  
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	Distributor	Class	Link
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### Anaesthetic and respiratory devices

New	LAVI 30 / LAVI 40	10/25/2017	Hoffrichter GmbH	AWAND EST. FOR MEDIC	FSN	<a href="#">A/Ca\</a>
New	TRACOE twist Tracheostomy Tube Size 06	10/23/2017	Tracoe medical GmbH	Arabian Trade House Est.	FSN	<a href="https://nc">https://nc</a>

### Assistive products for persons with disability

New	Liko Multirall 200 overhead lift and S65 Carriage	10/24/2017	Liko AB	N/A	2	<a href="https://nc">https://nc</a>
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### Dental devices

New	Orthodontic Skeletal Anchorage Screw ( O.S.A.S. Screws )	10/23/2017	Dewimed Medizintechnik GmbH	albasar for medical supplies	FSN	<a href="https://nc">https://nc</a>
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### Diagnostic and therapeutic radiation devices

Update	Accent/ Anthem, Accent MRI/ Accent ST, Assurity/ Allure and Assurity MRI devices	10/24/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
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### Electro mechanical medical devices

Update	Absorb GT1 Bioresorbable Vascular Scaffold Stents	10/24/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	2	<a href="https://nc">https://nc</a>
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New	Alaris Pump Module model 8100	10/24/2017	Becton, Dickinson And Company	Medical Regulations Gate	2	<a href="https">https</a>
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New	Curlin 6000 Painsmart IOD Infusion Pump Power Adapter Accessory	10/25/2017	Zevex International Inc	Abbott Laboratories	2	<a href="https://nc">https://nc</a>
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New	Hospira labelled MedNet Medication Management Suite – with Plum 360 Infusion System	10/25/2017	Hospira Inc	AL-KAMAL Import	1	<a href="https://nc.mdr">https://nc.mdr</a>
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New	Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor ,	10/24/2017	Radiometer America Inc	Salehiya Trading Est.	1	<a href="https://nc">https://nc</a>
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### Healthcare facility products and adaptations

New	V-PRO 60 Low Temperature Sterilization System	10/25/2017	Steris Corp	Arabian Medical Marketing Co. (AMCO)	FSN	<a href="https://nc">https://nc</a>
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### In vitro diagnostic devices

New	KAssay(R) MultiAnalyte Calibrator	10/24/2017	Kamiya Biomedical Company, LLC	Medical supplies & Services Co.Ltd	2	<a href="https">https</a>
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New	Alinity i Processing Module	10/25/2017	Abbott	Medical supplies & Services Co.Ltd	FSN	<a href="https">https</a>
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New	ARCHITECT c4000; ARCHITECT c8000; ARCHITECT c16000	10/23/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>
New	MIA FORA NGS	10/29/2017	BioArray Solutions Ltd	N/A	2	<a href="A/CaV">A/CaV</a>
New	oneHbA1c IS, Super ID HbA1c.	10/25/2017	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	<a href="https">https</a>
New	Radiometer ABL800 series with FLEXQ module	10/24/2017	Radiometer America Inc	Salehiya Trading Est.	1	<a href="https">https</a>
Update	VITEK 2 Gram-Positive (GP) Identification (ID) Test Kit	10/26/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc">https://nc</a>

### Laboratory equipment

New	Panther(R) System	10/24/2017	HOLOGIC NV	el Medical & Trading Co.	2	<a href="A/CaV">A/CaV</a>
New	Power Processor 1K Stockyard	10/25/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	<a href="https">https</a>

### Non-active implantable devices




New	Blades, Bone Cutting and Bur, orthopaedic	10/25/2017	Elva BV / Tava Surgical	N/A	FSN	<a href="https">https</a>
Update	Conformable GORE TAG Thoracic Endoprosthesis Devices	10/29/2017	W.L. Gore & Associates Inc.	Med Surg Supplies	1	<a href="https://nc">https://nc</a>
New	Dynlock Semi-rigid Stabilization System	10/25/2017	Sintea Plustek Srl	N/A	FSN	<a href="https">https</a>
New	EMPOWR PS KNEE(TM) e	10/24/2017	Encore Medical, Lp	Al Ewan Medical Compan	2	<a href="A/CaV">A/CaV</a>
New	FlexCath Advance Steerable Sheath	10/23/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https">https</a>



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New	Genesys spine, Binary Screwdriver	10/24/2017	Genesys Orthopedic Systems	N/A	2	<a href="https://nc">https</a>
New	GMK-HINGE	10/26/2017	Medacta International SA	N/A	FSN	<a href="A/CaV">A/CaV</a>
New	Oxford Dipper Hoist	10/24/2017	Sunrise Medical	Al-Enayah Company	2	<a href="A/CaV">A/CaV</a>
New	Pedicle System, Screw, Carbon/PEEK, Polyaxial	10/26/2017	icotec AG	N/A	FSN	<a href="https://nc">https</a>
New	Testicular Implant (Kiwee®) and Vaginal Stent	10/25/2017	Coloplast	janat al arab trading	FSN	<a href="https://nc">https://nc</a>
New	Thoracic Pedicle Feeler	10/25/2017	Stryker Trauma AG	I-Faisaliah Medical Syster	2	<a href="A/CaV">A/CaV</a>

### Ophthalmic and optical devices

New	Phaco-Handstück	10/25/2017	WEFIS GmbH	N/A	FSN	<a href="A/CaV">A/CaV</a>
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### Single-use devices

#	New	Convenience Kits Containing Medline Aplicare Povidone Iodine Prep Pads .	10/29/2017	Centurion Medical Products	Bio Standards	2	<a href="Attac hed">Attac hed</a>	
#	New	Covidien Argyle Suction Tubing ,	10/29/2017	Medtronic SA	Medtronic Saudi Arabia	2	<a href="Attac">Attac</a>	
	New	Dialysis Treatment Therapy Pack 105	10/29/2017	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	<a href="https://nc">https</a>	
	New	double lumen catheters ECLIPSE2L and COPERNIC2L	10/25/2017	Balt Extrusion.	Ikar Establishment	FSN	<a href="https://nc">https://nc</a>	
#	New	Green Polyisoprene Surgical Gloves with Aloe Vera	10/29/2017	Medline Industries Inc....	Ikar Establishment	2	<a href="Attac hed">Attac hed</a>	

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#	New	Harvest Graft Delivery GDP-10 Procedure Packs ,	10/29/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	<a href="#">Attac</a> 
#	New	Mahurkar Elite Acute Dual-Lumen Dialysis Catheters with Curved Extensions IC Trays ,	10/29/2017	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">Attac</a> <a href="#">hed</a> 
	New	WECK Auto Endo5 Automatic Hem-o-lok Clip	10/26/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="#">https</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.