



**SBED Weekly Update** 19-Sep-17

Dear,  
SBED team is pleased to inform you that **25** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 9/11/2017 to 9/17/2017  
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**

#	New	Bileaflet Mechanical Heart Valves.	9/13/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	<a href="#">Attac</a>
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**Anaesthetic and respiratory devices**

New	A.T.S 2200TS and A.T.S 4000TS	9/17/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="#">https</a>
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**Assistive products for persons with disability**

New	Powered Scooter	9/17/2017	Afikim Electric Vehicles	N/A	FSN	<a href="#">A/Ca</a>
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**Diagnostic and therapeutic radiation devices**


#	New	IntelliVue MX40 Patient-Worn Monitors	9/17/2017	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	2	<a href="#">Attac</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Mobile Detector Holders	9/11/2017	Philips Healthcare	s Healthcare Saudi Arabi	2	<a href="#">ttache</a> 



### Electro mechanical medical devices

#	New	Medfusion 4000 Wireless Syringe Infusion Pumps	9/17/2017	Smiths Medical, Inc	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attac</a> 
	New	MiniMed Infusion Sets	9/14/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="#">A/Cal</a>
#	New	Model 8100 Alaris Pump Modules.	9/13/2017	Becton, Dickinson And Company	Medical Regulations Gate	2	<a href="#">Attac</a> 
#	New	THERMOCOOL Catheters	9/17/2017	ebster Inc A Johnson & J	Saudi Import Co. Banaja	1	<a href="#">ttache</a> 

### In vitro diagnostic devices

	Update	Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit	9/17/2017	Abbott Molecular Inc Sub Abbott Laboratories	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>
#	New	ARCHITECT Analyzers and cSystems	9/17/2017	Abbott	Medical supplies & Services Co.Ltd	2	<a href="#">Attac</a> 
	New	AUTOCHECK5+ LEVEL 2	9/17/2017	Radiometer America Inc	Salehiya Trading Est.	FSN	<a href="#">A/Cal</a>


### Laboratory equipment

#	New	Alinity hq Analyzers	9/13/2017	Abbott	upplies & Services Co.Ltd	2	<a href="#">ttache</a> 
#	New	Alinity hq Analyzers	9/17/2017	Abbott	upplies & Services Co.Ltd	2	<a href="#">ttache</a> 

### Medical software

	New	Vanguard Open Box Femoral Component	9/17/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="https">https</a>
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### Non-active implantable devices

#	New	Cohesive I Siltex Round Ultra High Profile Gel Breast Implants	9/17/2017	Mentor Medical Systems	N/A	2	<a href="#">Attac hed</a> 
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Ziptight Ankle Syndesmosis Fixation Systems	9/17/2017	Zimmer, INC....	Medical Regulations Gate	2	<a href="#">Attached</a>

### Ophthalmic and optical devices

New	EC-3 Posterior Chamber Hydrophobic Acrylic Lens	9/17/2017	Aaren Scientific, Incorporated	N/A	FSN	<a href="#">https</a>
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### Single-use devices

# New	Alcohol Pads and Benzalkonium Chloride Antiseptic Towelettes	9/13/2017	Foshan Flying Medical Products	N/A	2	<a href="#">Attached</a>
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New	Intergard Woven	9/17/2017	InterVascular SA	Saudi Sicli Company	FSN	<a href="#">A/Cal</a>
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# New	Sage Products Oral Care Products Contained in Presource Kits	9/17/2017	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attached</a>
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Update	SPS-1 Static Preservation Solution	9/14/2017	Organ Recovery Systems	Altawn medical EST	2	<a href="#">https</a>
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# Update	Sterile Water, Saline and Eye Wash	9/13/2017	Smiths Medical International Limited	almadar medical Est.	FSN	<a href="#">Attac</a>
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# New	TCC-EZ Casts	9/17/2017	Integra LifeSciences	Bio Standards	2	<a href="#">ttache</a>
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New	Vicryl Rapide	9/17/2017	Ethicon Inc.	ohnson Medical Saudi Ar	FSN	<a href="#">A/Cal</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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- \* 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.