



**SBED Weekly Update** 26-Jun-17


Dear,  
SBED team is pleased to inform you that **22** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 6/19/2017 to 6/24/2017  
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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**Diagnostic and therapeutic radiation devices**



	New	2 over 2 Elevating Monitor Suspension pillar/column accessory	6/24/2017	Omega Medical Imaging, Inc.	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
#	New	CADstream Software	6/19/2017	Merge Healthcare Corp.	N/A	2	<a href="#">A/Ca</a>
	New	Merge PACS software ,	6/23/2017	Merge Healthcare Corp.	N/A	2	<a href="#">A/Ca</a>
	New	Merge PACS software ,	6/23/2017	Merge Healthcare Corp.	N/A	2	<a href="#">A/Ca</a>
	New	Proteus 235	6/24/2017	on Beam Applications S.A	N/A	2	<a href="#">A/Ca</a>
	New	SOMATOM Perspective, SOMATOM Scope Power, and SOMATOM Scope	6/24/2017	SIEMENS	Siemens Medical Solutions	2	<a href="https://nc.mdr">https://nc.mdr</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Various Ultrasound Systems	6/19/2017	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	

### Electro mechanical medical devices

#	New	Accu2i pMTA Applicators	6/19/2017	AngioDynamics Inc	MAAMOUN TAMER & C	2	
	New	AK 98, 230V, Bio .	6/22/2017	Baxter Healthcare	Baxter AG	FSN	<a href="#">A/Cal</a>
	New	Encore™ 26 Inflation Device Single Pack	6/20/2017	Boston Scientific	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>
#	New	Model 8015 Alaris System PC Units,	6/19/2017	BD Biosciences	Becton Dickinson B.V.	2	
#	New	Model 8100 Alaris Pump Modules and Pump Module Door Latch Kits	6/19/2017	BD Biosciences	Becton Dickinson B.V.	2	
	New	ROTH MOBELI grab handles used with EOS System	6/22/2017	EOS Imaging	Bio Standards	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
#	New	Visualase Cooled Laser Applicator System 15 mm Tip Caps	6/19/2017	Medtronic SA	Medtronic Saudi Arabia	2	


### In vitro diagnostic devices

#	New	Sample Mixer 2 Devices	6/21/2017	Exact Sciences	N/A	2	
#	New	Synchron Systems AQUA Cal 1 Reagents	6/19/2017	Beckman Coulter UK Ltd	Beckmancoulter INT L	2	

### Medical software

	New	MOSAIQ Radiation Oncology,	6/21/2017	IMPAC Medical Systems Inc	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>
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### Non-active implantable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Exeter Stems.	6/21/2017	Stryker Communications	I-Faisaliah Medical Syster	2	
Update	HeartMate 3 Left Ventricular Assist System (LVAS) ,	6/22/2017	Thoratec Corp	Arabian Trade House Est.	2	<a href="https://ncmdr">https://ncmdr</a>

### Single-use devices

# New	CADD High-Volume Administration Sets	6/19/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	
# New	GLIDESHEATH SLENDER Introducer Sheaths	6/19/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	
New	Sheridan SHER-I-SLIP and SOFT-TIP Intubating Stylets	6/23/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="https://ncmdr">https://ncmdr</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.