



**SBED Weekly Update** 24-Oct-17

Dear,

SBED team is pleased to inform you that **30** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 10/16/2017 to 10/22/2017  
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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**Anaesthetic and respiratory devices**

	New	Pulsavac Plus System	10/17/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="#">A/CaV</a>
#	New	Pure Stationary Oxygen Concentrators ,	10/22/2017	Inovo, Inc	N/A	2	<a href="#">A/CaV</a>

**Dental devices**

	New	Abut Gold Friction-Fit	10/19/2017	Biomet 3i Inc	Asnan Medical Services	2	<a href="#">A/CaV</a>
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**Diagnostic and therapeutic radiation devices**



	New	Integra CUSA Clarity Footswitch packaged with CUSA Clarity Console (Ref C7000	10/17/2017	Integra LifeSciences	Bio Standards	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
	New	Kalare (DREXKL80)	10/18/2017	ja Medical Systems Corpo	Gulf Medical Co.	2	<a href="#">A/CaV</a>

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### Electro mechanical medical devices



#	New	CADD Blue-Striped Administration Sets	10/16/2017	Smiths Medical, Inc	MEDICARE DRUG STORE COMPANY	2		
	New	CareLink iPro Therapy Management Software	10/16/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="#">https</a>	
	New	Catheter Mount Split Tubing Cuff	10/16/2017	Fisher & Paykel Healthcare Inc	Saudi Health Services Co. Ltd.	FSN	<a href="#">https</a>	
	Update	Catheter Mount Split Tubing Cuff	10/17/2017	Fisher & Paykel Healthcare Inc	Saudi Health Services Co. Ltd.	FSN	<a href="#">https</a>	
#	New	heartStart MRx Monitor/Defibrillator EtCO2 Modules ,	10/16/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2		
	New	O-arm O2 Surgical Imaging System	10/19/2017	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">https</a>	

### In vitro diagnostic devices

#	New	AQUIOS CL Flow Cytometry Systems	10/16/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2		
	New	MiSeqDx Instrument	10/19/2017	Illumina Inc	N/A	FSN	<a href="#">A/Ca\</a>	
#	New	RAPIDQC Complete Solution Used with RAPIDLab and RAPIDPoint Systems	10/16/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	2		
	New	Salmonella Antiserum ,	10/18/2017	Bio Rad.	el Medical & Trading Co.	FSN	<a href="#">A/Ca\</a>	
	New	Xpert EV Assay	10/19/2017	Cepheid	LA FOUAD HOLDING CO	2	<a href="#">A/Ca\</a>	

### Non-active implantable devices



	New	Anaconda	10/17/2017	cardiovascular Systems Co	ULREHMAN AL GOSAIBI	FSN	<a href="#">A/Ca\</a>	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	ENTACT SEPTAL STAPLER 3-PACK	10/17/2017	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="https://nc">https://nc</a>
New	Gyrus ACMI Round Cutting Burr - Variable Exposure	10/17/2017	Olympus	Salehiya Trading Est.	FSN	<a href="https://nc">https://nc</a>
# New	PASS OCT Pedicle Screwdriver Shafts	10/17/2017	Medicrea International.	Salehiya Trading Est.	2	
# New	Schanz Self-Drilling Screws,	10/16/2017	MicroPort Orthopedics	New Alnaser Medical Establishment	2	
New	Vanguard CR Tibial Bearing	10/17/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>


### Reusable devices

# New	Lancets, Blood	10/22/2017	Intrinsyk LLC	aka Wa AlBasata Compan	2	
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### Single-use devices

# New	5 Fr x 65 cm Soft-Vu Omni Flush Angiographic Catheters ,	10/17/2017	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	
# New	Degania Silicone Jackson- Pratt Drains	10/17/2017	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	
New	Intravenous administration tubing extension	10/17/2017	ICU Medical, Inc	AL-KAMAL Import	FSN	<a href="https://nc">https://nc</a>
# New	Medline Aplicare Povidone Iodine Prep Pads ,	10/17/2017	McKesson Provider Technologies	N/A	2	
New	PERFUSION TUBING SYSTEMS (PTS)	10/19/2017	LivaNova PLC	cigalah group	FSN	<a href="https://nc">https://nc</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Various Safeset and Transpac Blood Pressure Transducer Sets,	10/19/2017	ICU Medical, Inc	AL-KAMAL Import	2	<a href="https://nc">https://nc</a>
Update	Vascular cannula/catheter accessories, guidewire. Duowire.	10/19/2017	Coloplast	janat al arab trading	FSN	<a href="https://nc">https://nc</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.