



**SBED Weekly Update** 14-Jan-16

Dear,  
SBED team is pleased to inform you that **48** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 1/4/2016 to 1/10/2016  
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	Evita V500 Ventilator and Babylog VN500 Ventilator	1/4/2016	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	1	<a href="#">http:</a>
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# New Oxylog Ventilators 1/5/2016 raeger Medical Systems Ir Draeger Arabia Co. Ltd. 1 [ttache](#)

New	WaterPAP Positive Airway Pressure Device	1/4/2016	Airways Development LLC	N/A	2	<a href="#">http:</a>
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**Assistive products for persons with disability**




New	Contender Post-op-Knee Brace Lite	1/10/2016	Corflex	husn al Emirat Est.	2	<a href="#">http:</a>
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**Dental devices**



New	ART 1036 Radiographic Transparency	1/5/2016	Biomet 3i Inc	Asnan Medical Services	2	<a href="#">http:</a>
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### Diagnostic and therapeutic radiation devices

	New	Dressit-X	1/4/2016	ow Specialty & Health Pro	N/A	2	<a href="#">A/Cal</a>
#	New	Mavig Monitor Suspension Arms Used with Various Fluoroscopic Imaging Systems	1/5/2016	GE Healthcare	GE Healthcare	2	<a href="#">Attac hed</a> 
#	New	Superconducting Magnets	1/5/2016	SIEMENS	iemens Medical Solution	2	<a href="#">ttache</a> 
#	New	Various Duodenoscopes	1/5/2016	FUJIFILM Medical Systems	MAAMOUN TAMER & C	2	<a href="#">ttache</a> 

### Electro mechanical medical devices

	New	Battery Oscillator II, handpiece.	1/6/2016	Synthes Inc	Isam Economic Co.	FSN	<a href="#">http:</a>
	New	CNSystems TASK FORCE MONITOR 3040i	1/10/2016	CNSystems Medizintechnik AG	Almarfa Medical	2	<a href="#">http:</a>
	New	INNOVANCE PFA P2Y	1/6/2016	SIEMENS	iemens Medical Solution	FSN	<a href="#">A/Cal</a>
#	New	Liberty Cyclor Machines	1/5/2016	Fresenius Medical Care	Saudi Renal Services Ltd.	2	<a href="#">ttache</a> 
	New	Merge Hemo and Merge Cardio	1/4/2016	Merge Healthcare Corp.	N/A	2	<a href="#">http:</a>
	New	Powerheart G3 defibrillation electrodes	1/6/2016	Cardiac Science Corporation	Mohammed Binmahfouz Trading Est	FSN	<a href="#">http:</a>
	New	Remote Patient Monitoring System	1/10/2016	Vidco, Inc.	N/A	2	<a href="#">http:</a>
#	New	Symbiq Infusion Pump System Pole Clamp Assemblies	1/5/2016	Hospira Inc	AL-KAMAL Import	2	<a href="#">Attac hed</a> 

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# New	TLC Self-Retaining Retractor Frames, TLC Self-Retaining Retractor Systems, and Wilson Penile Implantation Systems	1/5/2016	Abeon Medical	N/A	2	<a href="#">Attached</a>
New	VAPR TRIPOLAR 90" Degree Suction Electrodes	1/4/2016	DePuy International Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="#">http:</a>

### Healthcare facility products and adaptations

New	TruLight 3000, TruLight 5000, iLED 3, iLED 5 and TruVidia Lighting and Video Systems	1/7/2016	Trumpf Medical Systems, Inc.	Medical regulations gate	2	<a href="#">http://ncmdr.</a>
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### Hospital hardware

New	Concerto & Basic shower trolley	1/7/2016	Arjo Huntleigh	Al-Faisaliah Medical System	FSN	<a href="#">http:</a>
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### In vitro diagnostic devices

New	API ZYM B	1/7/2016	bioMerieux Inc	el Medical & Trading Co.	2	<a href="#">A/CaV</a>
New	AQURE system	1/6/2016	Radiometer America Inc	Salehiya Trading Est.	FSN	<a href="#">A/CaV</a>
Update	BD BBL Vancomycin Screen Agar	1/4/2016	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	<a href="#">http:</a>
New	CAPILLARYS 3 TERA	1/10/2016	SEBIA	Al-Zahrawi Medical Co.	FSN	<a href="#">A/CaV</a>
# New	DensiCHEK Plus Units Used with VITEK 2 Systems	1/5/2016	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	<a href="#">Attached</a>
New	FB Broth	1/4/2016	Hardy Diagnostics	N/A	2	<a href="#">A/CaV</a>
New	ImmunoCAP Specific IgG/IgG4 i1 Control H	1/7/2016	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="#">http:</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	SPOTCHEM II Reagent Test Strips	1/5/2016	ARKRAY	Zimmo Trading Establishment.	2	<a href="#">Attac</a>
Update	VITROS Chemistry Products Calibrator Kit 9	1/7/2016	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	1	<a href="#">http:</a>

### Non-active implantable devices

New	ala purple	1/6/2016	alamedics GmbH & Co. KG	Saad Al Bashir	FSN	<a href="#">A/CaV</a>
# New	CARDIOSAVE Hybrid and CARDIOSAVE Rescue Intra-Aortic Balloon Pumps	1/5/2016	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	2	<a href="#">http://nc.mdr.</a>
New	Hip Preservation System Signature PreBent Burs	1/7/2016	ConMed Corporation	Saudi Import Co. Banaja	FSN	<a href="#">http:</a>
New	PFNA Nails	1/7/2016	DePuySynthes	Isam Economic Co.	2	<a href="#">A/CaV</a>
New	sterile pack. Guide wires, K-Wires , Metaizeau pin	1/6/2016	Stryker Communications	Al-Faisaliah Medical System	FSN	<a href="#">http:</a>
New	Total Toe Instrument Kit	1/4/2016	Arthrosurface, Inc.	N/A	2	<a href="#">A/CaV</a>
New	VariAx 2 3.5 mm screws, Included in VariAx Compression EPS system tray	1/7/2016	Stryker Communications	Al-Faisaliah Medical System	2	<a href="#">http://nc.mdr.</a>
New	Vortek - Single Loop Ureteral Stent	1/6/2016	Coloplast	janat al arab trading	FSN	<a href="#">http:</a>
New	Zilver 518RX Vascular Stent	1/6/2016	Cook Inc,	NAFA Medical	FSN	<a href="#">http:</a>
New	Zimmer Universal Locking System.	1/6/2016	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="#">http:</a>

### Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Disposable Kwik Fix short service sling – DHECL	1/7/2016	Silvalea	N/A	FSN	<a href="http://nc">http://nc</a>
New	Enteral feeding sets: Compat Gravity; Compat Standard	1/10/2016	CEDIC SRL	N/A	FSN	<a href="http://nc">http://nc</a>

### Single-use devices

New	Cardinal Health Tiny Toes	1/4/2016	Philips Healthcare	s Healthcare Saudi Arabi	2	<a href="A/CA">A/CA</a>
New	Citra-Lock 5 4%	1/7/2016	edisp Produtos Hospitalar	N/A	FSN	<a href="A/CA">A/CA</a>
New	CME Syringe Extension sets for use with the CME T34/T60 pumps	1/7/2016	CME America, LLC	N/A	FSN	<a href="http://nc">http://nc</a>
New	Green and Black Mamba Suture Passer	1/4/2016	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	<a href="http://nc">http://nc</a>
New	NS2 6FR DEHP Free PVC tube 75CM XRO	1/6/2016	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="http://nc">http://nc</a>
New	PiCSO® Impulse System	1/7/2016	Miracor Medical Systems	cal Technology Establish	FSN	<a href="A/CA">A/CA</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.sfd.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.