



SBED Weekly Update 04-Dec-18

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 11/26/2018 to 12/2/2018  
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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**Active Implantable Devices**

# Update	TB-Temporary Bipolar Pacing Leads	11/28/2018	Oscor Inc.	Medical Technology Trading Company	FSN	<a href="#">Attac hed</a>	
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**Assistive products for persons with disability**

New	PremierPro Aluminum Adjustable Walker	11/26/2018	SVS LLC	N/A	2	<a href="https://nc">https://nc</a>	
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**Diagnostic and therapeutic radiation devices**

New	DX-D 600 X-ray system	11/28/2018	AGFA Corp.	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>	
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New	Multiple GE MRI systems	11/28/2018	GE Healthcare	GE Healthcare	FSN	<a href="https://nc">https://nc</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Operating Room Tables (T2X, ORT1 00, ORT200, ORT300)	11/27/2018	IMRIS Inc.	Gulf Medical Co.	FSN	<a href="https://nc.mdr.">https://nc.mdr.</a>	

# New	RADREX-i Digital Radiography System Wireless Flat-Panel Detectors	11/28/2018	Canon Inc	Gulf Medical Co.	2	<a href="#">Attached</a>	
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New	RayStation 3.5, RayStation 4.0, RayStation 4.5, RayStation 4.7, RayStation 5, RayStation 6, RayStation 7, and RayStation 8A	11/29/2018	RaySearch Laboratories AB	Creative Healthcare Establishment	2	<a href="https://nc.mdr.sfda.gov.sa/Secure/">https://nc.mdr.sfda.gov.sa/Secure/</a>	
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# New	Xper Flex Cardio Patient Monitoring Systems (FC2010, FC2020)	11/28/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="#">Attached</a>	
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### Electro mechanical medical devices

# New	General-Purpose Temperature Probes ,	11/28/2018	Med-link	N/A	2	<a href="#">Attached</a>	
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New	Heater-Cooler Unit HCU 40 , HCU40	11/27/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	<a href="https://nc.">https://nc.</a>	
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New	Medtronic HeartWare HVAD System Battery Charger ,	12/2/2018	Medtronic SA	Medtronic Saudi Arabia	1	<a href="https://nc.mdr.">https://nc.mdr.</a>	
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# New	Optiflux F160NR Dialyzers	#####	Fresenius Medical Care.	senius Medical Care Gmt	2	<a href="#">ttache</a>	
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# New	Synovis GEM4183C Coupler Forceps	11/28/2018	Synovis Surgical Innovations Div Synovis	Al-Nozha Medical Est	2	<a href="#">Attached</a>	
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### Healthcare facility products and adaptations

New	Salus-10-AM-EU	#####	SciCan Ltd.	n Medical Instruments C	FSN	<a href="#">A/Cal</a>	
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### In vitro diagnostic devices

New	Alere BinaxNOW Legionella with the Alere Reader	11/26/2018	Alere International Limited	Fuad Abdul Jalil Al Fadhli & Sons	FSN	<a href="https://nc.mdr">https://nc.mdr</a>	
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New	Evidence Investigator	#####	Randox Laboratories Ltd.	Bio Standards	FSN	<a href="A/Ca">A/Ca</a>	
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New	FTIyo 2+.1 Respiratory pathogens 21 plus; FTIyo 2P.3 Respiratory pathogens 33; FTIyo 48.1 FLU/HRSV v.2; FTIyo 56.1 HCoV v.1	11/26/2018	Fast Track Diagnostics Luxembourg S.à.r.l.	N/A	FSN	<a href="https://nc.mdr.sfda.gov.sa/Sec">https://nc.mdr.sfda.gov.sa/Sec</a>	
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New	gabControl, Hitado, DiaTest, IDEAL H. pylori	11/27/2018	gabmed	N/A	FSN	<a href="https://nc">https://nc</a>	
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#	New	Hemoglobin A1c Controls..	11/28/2018	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	2	<a href="Attac hed">Attac hed</a>	
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New	NADAL PROM Amniotic fluid Test	11/27/2018	nal von minden GmbH	Dal Pharma	FSN	<a href="https://nc">https://nc</a>	
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New	ORG 242G Anti-alpha-Fodrin IgG	11/27/2018	ORGENTEC Diagnostika GmbH	REDWAN MEDICAL SERVICES	FSN	<a href="https://nc">https://nc</a>	
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New	ORG 243M Anti-Annexin V IgM	11/27/2018	ORGENTEC Diagnostika GmbH	REDWAN MEDICAL SERVICES	FSN	<a href="https://nc">https://nc</a>	
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New	Oxoid Brilliance VRE Agar	11/27/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	FSN	<a href="https://nc">https://nc</a>	
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New	PakAuto	#####	Immucor GmbH.	pplies & Services Co.Ltd	FSN	<a href="A/Ca">A/Ca</a>	
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New	Ratiomed H. pylori	#####	megro GmbH & Co. KG	N/A	FSN	<a href="A/Ca">A/Ca</a>	
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New	Tosoh AIA-900 immunoassay Analyzer	11/26/2018	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	2	<a href="https://nc">https://nc</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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### Laboratory equipment

New	BD Vacutainer Urine Cups	11/27/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	<a href="https://nc">https://nc</a>	
New	DeltaVision OMX SR Imaging System	11/26/2018	GE Healthcare	GE Healthcare	2	<a href="https://nc">https://nc</a>	

### Non-active implantable devices

New	BiMobile Cup C, Liner, UHMWPE	11/27/2018	Waldemar LINK GmbH & Co	Abdul Jaleel Ibrahim Batterjee Sons	FSN	<a href="https://nc">https://nc</a>	
# New	Double Trocar and Trocar Tip K-Wires ,	11/28/2018	Ortho Solutions	N/A	2	<a href="https://nc">https://nc</a>	
New	Medtronic StrataMR Guider Tool	11/27/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https://nc">https://nc</a>	
New	mont blanc MIS, Posterior fusion minimal invasive spine surgery	11/27/2018	Spineway SA	AL HABIB COMPANY For Trading, Comml,Contracts Ltd	FSN	<a href="https://nc">https://nc</a> <a href="https://nc">mdr.</a>	
New	NexGen Complete Knee Solution Femoral Augment Block Distal Only	11/26/2018	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a> <a href="https://nc">mdr.</a> <a href="https://nc">sfda.</a>	
New	Vanguard Knee System PS Open Box Femoral Right and left	11/27/2018	Zimmer, INC....	Medical Regulations Gate	2	<a href="https://nc">https://nc</a> <a href="https://nc">mdr.</a>	

### Ophthalmic and optical devices

New	Artelac Rebalance EDO /Artelac Rebalance SDU	11/27/2018	Bausch & Lomb GmbH..	Medical regulations gate	FSN	<a href="https://nc">https://nc</a>	
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### Single-use devices

# New	0.9% Sodium Chloride Injections	11/28/2018	Fresenius Kabi AG	Alhaya medical co.	2	<a href="https://nc">https://nc</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Medicina CG Nasogastric Tubes ,	12/2/2018	Medicina	Al Hammad Medical Services	2	<a href="https://nc">https://nc</a>	
New	Minisart NML	#####	torius Stedim Biotech Gm	N/A	FSN	<a href="#">A/Ca\</a>	
# New	Prestrol Suction Catheters	#####	Pennine Healthcare	CARE DRUG STORE COM	2	<a href="#">ttache</a>	
New	Suction/Anticoagulation Assembly Lines	11/29/2018	Medtronic SA	Medtronic Saudi Arabia	2	<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.