



SBED Weekly Update

03-Jan-18

Dear,

SBED team is pleased to inform you that **37** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 12/25/2017 to 12/31/2017
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	Distributor	Class	Link
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Active Implantable Devices

New	SynCardia Freedom Driver System ,	12/26/2017	SynCardia Systems Inc	Arabian Trade House Est.	2	https
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Anaesthetic and respiratory devices

#	New	AirLife Humidification Chambers and Heated Breathing Circuits ,	12/26/2017	Vyaire Medical	N/A	2	
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New	PMH7000 series Heated humidifiers	12/31/2017	Pacific Medico Co., Ltd	N/A	FSN	https
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Assistive products for persons with disability

New	Andago V2.0	12/26/2017	Hocoma AG	Dar Cima Est	FSN	A/Ca
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Dental devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Portable Dental Unit DU893	12/31/2017	Shanghai International Holding Corp. GmbH	N/A	FSN	https

Diagnostic and therapeutic radiation devices

New	Allura Xper systems ,	12/26/2017	Philips Healthcare	s Healthcare Saudi Arabi	FSN	A/Ca\
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New	Examiner 3DX 6000 StandAlone & InLine Systems	12/25/2017	L3 Security & Detection	N/A	2	https ://nc
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New	Ingenuity TF PET/CT ,	12/28/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https
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# New	Monica Novii Wireless Patch System ,	12/26/2017	GE Healthcare	GE Healthcare	2	
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New	TomoHDA System	12/28/2017	Accuray Inc	Gulf Medical Co.	2	A/Ca\
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New	ULTRASOUND SYSTEM SONIMAGE HS1	12/26/2017	KONICA MINOLTA, INC	Ahmed Abdulwahed Trading Co	FSN	https
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Electro mechanical medical devices


New	ClearSight Heart Reference Sensor ,	12/28/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	https
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New	Signia Power Handle	12/25/2017	Medtronic SA	Medtronic Saudi Arabia	2	A/Ca\
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New	Stroke Fast Pack.	12/25/2017	Stryker Neurovascular	MAAMOUN TAMER & C	2	A/Ca\
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In vitro diagnostic devices

New	cobas u 601 / cobas u 701 ,	12/27/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
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# New	Dimension Lipase Assays ,	12/26/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	DuraClone B27 Reagent Kit	12/26/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
New	ETEST Teicoplanin 256 (TP) SPB and Foam packaging.	12/26/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc
New	HbA1c	12/25/2017	Randox Laboratories Ltd.	Bio Standards	2	A/Ca
New	Hemoglobin A1c (HbA1c) Reagent	12/26/2017	Abbott	Medical supplies & Services Co.Ltd	FSN	https://nc
# New	uTYPE Dx v1.0 HLA Sequence Analysis Software	12/26/2017	One Lambda Inc	Farabi Trading Establishment	2	
New	VITEK 2 Antimicrobial Susceptibility Test Kit (AST)	12/31/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
New	VITROS Chemistry Products PHYT Slides	12/25/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	https://nc

Non-active implantable devices

New	DePuy Synthes Confidence Kit Spinal Cement System ,	12/26/2017	Medos International SARL.	Johnson & Johnson Medical Saudi Arabia Limited	FSN	https://nc
New	Integra Cadence Total Ankle System- Case for Trials, Insertion and Removal instruments (Insert Instrument Set)	12/31/2017	Integra LifeSciences	Bio Standards	FSN	https://nc mdr sfda
New	Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling	12/26/2017	Coloplast	janat al arab trading	2	https://nc mdr


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Sealed/unsealed Polyester & ePTFE Vascular Grafts	12/26/2017	Vascutek Limited	Gulf Medical Co.	FSN	https://nc

Ophthalmic and optical devices

New	1-DAY ACUVUE MOIST Brand Contact Lenses.	12/26/2017	Johnson & Johnson Vision Care	Allied Medical International	FSN	https
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Single-use devices

New	Gambro BL105 und Gambro BL208BD	12/31/2017	Gambro Lundia AB	Baxter AG	FSN	https
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#	New	MediChoice Kits and Trays Containing Medline Aplicare Povidone Iodine Prep Pads	12/26/2017	Owens & Minor	N/A	2	
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New	Medtronic Clip Gun™ Scalp Clip System	12/25/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https
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#	New	Metrex MetriCide OPA Plus	12/26/2017	Metrex Research, LLC	N/A	2	
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#	Update	Over-Pressure Safety Valves	12/26/2017	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	
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#	New	Prelude SNAP Splittable Sheath Introducers,	12/26/2017	Merit Medical Systems Inc	Majal Care for Trading Est.	2	
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New	SpyScope™ DS	12/26/2017	Boston Scientific	Gulf Medical Co.	FSN	A/Ca
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New	Vasco-OP Sensitive Gr.7 Sterile – Surgical Gloves	12/31/2017	B. Braun Melsungen AG	Cigalah Group	FSN	https
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New	VenaFlow Calf Garment (Aircast)	12/25/2017	Stryker Sustainability Solutions	N/A	2	https
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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.