



SBED Weekly Update 12-Dec-17

Dear,
SBED team is pleased to inform you that **50** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 12/4/2017 to 12/10/2017
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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Active Implantable Devices

New	Nanostim Leadless Pacemaker	12/6/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
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Anaesthetic and respiratory devices

New	Airsep Impulse Elite	12/10/2017	AirSep Corporation..	R HEALTHCARE SAUDI A	2	A/CaV
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Assistive products for persons with disability

#	New	Posture Belts and Posture Harnesses on KATO Plus Seating Systems	12/5/2017	Chas A Blatchford & Sons Ltd	husn al Emirat Est.	2	
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New	Morning Life	12/10/2017	Won Industry Co.	N/A	2	A/CaV
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New	Multicare	12/10/2017	Linet spol. s r.o.	Salehiya Trading Est.	FSN	A/CaV
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Dental devices

	New	Legacy 3 Implant	12/4/2017	Direct Sybron Manufactur	Abdullah Alzoman Est. for	2	A/Ca
#	New	Tapered Screw-Vent MTX Full Textured Implants	12/10/2017	Biomet 3i Inc	Asnan Medical Services	2	

Diagnostic and therapeutic radiation devices

	New	Brainlab Navigation System Spine & Trauma 3D	12/6/2017	BrainLAB	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr
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#	New	Brilliance iCT, Brilliance 64, Ingenuity Core, and Ingenuity Core128 Computed Tomography Systems ,	12/4/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	
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	New	CombiDiagnost	12/6/2017	Philips Healthcare	s Healthcare Saudi Arabia	FSN	A/Ca
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	New	High Power Handheld Laser	12/10/2017	United Nuclear Scientific Supplies, LLC	N/A	2	https://nc
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	New	IVIEWGT SYSTEM	12/4/2017	Elekta Inc	Medical Regulations Gate	FSN	A/Ca
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	New	MHI-TM2000 / Vero Linac System..	12/6/2017	Hitachi Medical Corp	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc
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	New	ProteusPLUS, ProteusONE	12/10/2017	IBA Dosimetry GmbH	I-Faisaliah Medical Syster	FSN	A/Ca
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	New	Sonallev MR-HIFU.	12/10/2017	Philips Healthcare	s Healthcare Saudi Arabia	FSN	A/Ca
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	New	Volcano s5i, CORE and CORE Mobile systems	12/5/2017	VOLCANO CORPORATION	Ikar Establishment	2	https://nc
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	New	Vyntus BODY with Option Diffusion	12/10/2017	CareFusion	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
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Electro mechanical medical devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Everflex SelfExpanding Peripheral Stent with Entrust Delivery System	12/4/2017	Medtronic SA	Medtronic Saudi Arabia	2	https://nc.mdr

#	New	Gen 11 Systems ,	12/4/2017	Ethicon Inc.	Johnson Medical Saudi Ar	2	Link	
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#	New	Patient Care Console Modules for Xper Flex Cardio Patient Monitoring Systems,	12/4/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Link	
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New	SMARTABLATE System	12/10/2017	Biosense Webster Inc.	Johnson Medical Saudi Ar	2	A/Ca
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New	SMR Graft Cutter	12/5/2017	Limacorporate S.p.a.	N/A	FSN	A/Ca
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#	Update	Xper Flex Cardio Patient Monitoring Systems	12/5/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Link	
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In vitro diagnostic devices

Update	Accu-Chek Connect Diabetes Management App (iOS & Android)	12/10/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr
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#	Update	Elecsys Digoxin, cobas e 801 module	12/10/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	Link	
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Update	N Antiserum to Human Ceruloplasmin	12/4/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	2	https://nc.mdr
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New	oneHbA1c IS INNOVASTAR	12/10/2017	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	https://nc.mdr
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New	Phadia Prime with software up to and including version 2.1.4	12/7/2017	Phadia Ltd	ABDULREHMAN AL GOSAIBI GTB	2	https://nc.mdr
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New	Thermo Scientific Oxoid Mueller-Hinton Broth	12/5/2017	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	FSN	https://nc.mdr
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Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
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Non-active implantable devices

New	2M insert 15° for MUTARS RS cup and LUMiC TiN	12/10/2017	Implantcast	AlMafsal Medical Company	FSN	https://nc.mdr
New	Balt Cristal Balloons	12/7/2017	Balt Extrusion.	Ikar Establishment	1	A/CaV
New	CONELOG SCREW-LINE Implant, Promote plus, CAMLOG SCREW-LINE Implant, Promote und . CAMLOG SCREW-LINE Implant, Promote plus	12/10/2017	CAMLOG Biotechnologies AG	N/A	FSN	https://nc.mdr.sfda.gov.sa/Se
New	Everest Spinal System	12/10/2017	K2M Inc.	N/A	FSN	A/CaV
New	Irraflow Tube Set	12/10/2017	IRRAS AB Inc.	N/A	FSN	A/CaV
New	MobileLink Acetabular Cup System X-LINKed Insert	12/10/2017	Waldemar LINK GmbH & Co	Abdul Jaleel Ibrahim Batterjee Sons Development Co. Ltd.	FSN	https://nc.mdr
New	Plate for MUTARS Proximal Femur Revision	12/10/2017	Implantcast	AlMafsal Medical Company	FSN	https://nc
New	Premicath / Premistar	12/5/2017	Vygon UK Ltd	el Medical & Trading Co.	FSN	A/CaV
New	U2 Total Knee System Tibial Insert, PS & PSA	12/5/2017	United Orthopedic Corporation	N/A	FSN	https://nc
New	Vintage Total Ankle Tibia Insert	12/10/2017	Exactech	N/A	2	https://nc




Reusable devices

#	New	Rotating IV Poles Used with Various Infant Warmer Systems ,	12/10/2017	GE Healthcare	GE Healthcare	2	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	WASSENBURG WD440, WD440 PT, WD415	12/6/2017	WASSENBURG Medical B.V	Al Mofadaly Trading Est.	FSN	https://nc

Single-use devices

#	New	Dover Trays and Covidien Curity Kits Containing Medline/Apicare Povidone Iodine Prep Pads	12/10/2017	Medtronic SA	Medtronic Saudi Arabia	2		
	New	Adult Altius Central Venous Catheter Kit (K2CS / K2CV) - 18G Echogenic Introducer Needle	12/10/2017	Kimal Plc.	First Medical co. Ltd.	FSN	https://nc.mdr.sfda.gov.s	
#	New	Curlin Nonfiltered Intravenous Administration Sets .	12/10/2017	Moog Inc	N/A	2		
	New	DeRoyal Sterile Custom kits	12/10/2017	DeRoyal Industries Inc.	Alhaya medical co.	2	https://nc	
	New	Intro-Flex Automatic Hemostasis Valve Introducer	12/10/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	https://nc.mdr	
	New	man Pleural/Pneumopericardial Drainage Set	12/6/2017	Cook Inc,	NAFA Medical	FSN	https://nc.mdr	
#	New	Medical Action Industries Convenience Kits Containing Apicare Povidone Iodine Prep Pads ,	12/4/2017	Mckesson Information Solutions LLC	N/A	2		
	New	Perfusor compact plus	12/10/2017	B. Braun Melsungen AG	Cigalah Group	FSN	A/Ca	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Various Vital-Port Vascular Access Systems,	12/7/2017	Cook Medical	NAFA Medical	1	https://nc

- * 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.