



SBED Weekly Update 19-Jun-17

Dear,
SBED team is pleased to inform you that **42** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 6/12/2017 to 6/18/2017
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	Prometra II Programmable Pumps	6/12/2017	Flowonix Medical	N/A	1	
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Anaesthetic and respiratory devices


#	New	Various NIPPY Ventilators	6/13/2017	B&D Electromedical	N/A	2	
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Diagnostic and therapeutic radiation devices

New	Artis Systems in conjunction with the Artis table	6/15/2017	Siemens Medical Solutions	Siemens Medical Solutions	FSN	https://nc.mdr
New	Centricity Critical Care (CCC, formerly known as Clinisoft)	6/18/2017	GE Healthcare	GE Healthcare	FSN	https://nc.mdr

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Update	Infant Warmer System (IWS) Hot "Heater Head"	6/15/2017	GE Healthcare	GE Healthcare	FSN	https://nc
# New	IRIDICA Controller Software Used with IRDICA Bead Beater Systems	6/14/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	2	
New	Shimadzu Ceiling Type X-ray Tube Support ,	6/17/2017	Shimadzu Medical Systems..	Salehiya Trading Est.	2	https://nc
# Update	Shimadzu Ceiling Type X-ray Tube Support ,	6/18/2017	Shimadzu Medical Systems..	Salehiya Trading Est.	2	

Electro mechanical medical devices

New	ARROWgard Blue CVC, ARROW MAC TwoLumen Central Venous Access, Arrow Pressure Injectable PICC Kit	6/15/2017	Arrow International Inc	Gulf Medical Co.	3	https://nc.mdr.sfda.gov.s
# New	da Vinci Xi Surgical Systems	6/12/2017	Intuitive Surgical Inc	Gulf Medical Co.	2	
New	Flowtron ACS900	6/15/2017	jo Huntleigh - electric bec	Gulf Medical Co.	FSN	A/CaV
New	Organ Care System (OCS) Heart system	6/17/2017	TransMedics	N/A	2	https://nc
New	Philips IntelliVue MX40 Wearable Patient Monitors .	6/17/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https://nc.mdr
New	Rosa One 3.1	6/18/2017	Zimmer Biomet	n Medical Instruments Co	2	A/CaV
New	Sharesource Claria Connectivity Platform for Use with Homechoice Claria APD System	6/15/2017	Baxter Corp Canada	Baxter AG	FSN	https://nc.mdr.sfda





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New	Uterine Electromyographic Monitor	6/15/2017	GE Healthcare	GE Healthcare	2	https://ncmdr.

In vitro diagnostic devices

#	New	200 mg/100 mL Fluconazole Injections and 100 mL 20 mg/100 mL Milrinone Lactate 5% in Dextrose Injections in INTRAVIA Containers	6/12/2017	Baxter Corp Canada	Baxter AG	2	
	Update	ABL90Flex battery module used with Radiometer ABL90FLEX blood gas analyser (Optional battery)	6/17/2017	Radiometer America Inc	Salehiya Trading Est.	2	https://ncmdr.sfda.gov.s
	New	ASP6025 Tissue Processor	6/15/2017	Leica Microsystems, Inc.	Salehiya Trading Est.	FSN	A/Ca
	New	Calibrator 30 (2 pack) used with ADVIA Centaur Enhanced Estradiol (eE2) on the ADVIA Centaur, Centaur XP and Centaur XPT systems	6/18/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://ncmdr.sfda.gov.s/a/Se
	Update	cobas 8000 ISE module 900 / 1800, cobas c 311 / 501 / 502 / 701 / 702	6/15/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://ncmdr.
	New	cobas omni MGP Reagent when used with cobas MPX assay (for use on the cobas 6800/8800 systems)	6/17/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	https://ncmdr.sfda.gov.s
	New	Creatinine (Enzymatic)	6/15/2017	SENTINEL CH. SpA	Ipplies & Services Co.Ltd	FSN	A/Ca

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New	Phenocell B 0.8% and 3% and Abtectcell III 0.8%RhD	6/17/2017	Seqirus Pty Ltd	N/A	2	https://nc.mdr
New	Valproic Acid and Antibiotic TDM Multi-Calibrator	6/18/2017	Beckman Coulter UK Ltd	Beckmancoulter INT L	2	https://nc.mdr
New	Various Microgenics Application Sheets.	6/18/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	https://nc

Non-active implantable devices


New	29mm Blue REGUS Circular Stapler RCS-29	6/14/2017	Regus Surgical BVBA	N/A	FSN	https://nc	
#	New	58 mm PINNACLE Hip Sector DUOFIX HA Shells	6/14/2017	Depuy Orthopaedics, Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	
#	New	Atrium iCAST Balloon Expandable Covered Stents	6/12/2017	Getinge Disinfection AB	Gulf Medical Co.	2	
New	HeartMate 3 Left Ventricular Assist System (LVAS) ,	6/18/2017	Thoratec Corp	Arabian Trade House Est.	2	https://nc.mdr	
#	New	LATARJET EXPERIENCE Systems Instruments	6/14/2017	Depuy Orthopaedics, Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	
#	New	Various Prosthesis Components	6/14/2017	aap Implantate AG	Saudi Import Co. Banaja	2	

Single-use devices

#	New	60-Inch Enteral Extension Sets	6/12/2017	Kentec Medical Inc	N/A	2	
New	Aortic Arch Cannula..	6/15/2017	Sorin Group	Arabian Trade House Est.	FSN	A/Ca	

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#	New	ChloraPrep Skin Preparation Applicators Contained in GYN Laparoscopy Complete Delivery Systems	6/12/2017	Medline Industries Inc...	Ikar Establishment	2	
#	New	Double-Wrapped Gauze Swabs Contained in Various Guardian Procedure Packs	6/14/2017	Guardian Surgical	N/A	2	
#	New	Insulin Syringes with BD Ultra-Fine Needles	6/12/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	
#	New	PrecisionGlide Needles	6/12/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	
#	New	Sirus Gowns Poly Reinforced with Breathable Sleeve	6/18/2017	Master & Frank Enterprise Co Ltd	N/A	2	
#	New	Sterilmed SOUNDSTAR eco Catheters Used with CARTO 3 or CARTO XP Navigation Systems	6/18/2017	Biosense Webster Inc A Johnson & Johnson Co.	Saudi Import Co. Banaja	2	
	Update	VueOptic Visualisation Source & Flexor Vue Deflecting Endoscopic System	6/15/2017	Cook Medical	NAFA Medical	2	https://nc.mdr.sfda
	Update	Zurpaz Steerable Sheath 8.5F Asymmetric and Symmetric Curve	6/15/2017	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr

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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.