



SBED Weekly Update 07-Nov-17

Dear,
SBED team is pleased to inform you that **44** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/30/2017 to 11/5/2017
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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Assistive products for persons with disability

#	Update	A-series lift - A625	10/30/2017	Ergosafe Products LLC	N/A	2	ttache
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Dental devices

	New	SimplyInterActive Implant,	11/2/2017	Direct Sybron Manufactu	Abdullah Alzoman Est. fo	FSN	A/Cal
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Diagnostic and therapeutic radiation devices

	New	Ablatherm Integrated Imaging device	10/30/2017	EDAP TMS FRANCE SAS,	Dar Al-Zahrawi Medical Co. LLC	2	https
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	New	Drystar DT 2 C Hardcopy Film 14" x 17"	11/2/2017	AGFA Corp.	Gulf Medical Co.	2	https
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Electro mechanical medical devices

#	Update	ARCTIC SUN 5000 Temperature Management Systems ,	10/30/2017	C R Bard Inc	C.R. BARD Saudi Arabia	2	Attac hed
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Giraffe OmniBed, Incubator, OmniBed Carestation, and Incubator Carestation Systems ,	11/5/2017	GE Healthcare	GE Healthcare	2	Attac hed 
# Update	HomeChoice and HomeChoice PRO Automated PD Cyclers	10/30/2017	Baxter Corp Canada	Baxter AG	2	Attac hed 
New	Plum 360 Infusion System ,	10/31/2017	Hospira Inc	AL-KAMAL Import	2	https
# New	Slim Headphones for Audio Systems	10/30/2017	NordicNeuroLab Inc.	N/A	2	Attac hed 
# New	Summit Doppler 2 MHz Waterproof OB Probes	11/5/2017	Cooper Surgical, Inc.	Cure Development International Ltd	2	Attac hed 
New	THERMI250 Radiofrequency System	10/30/2017	Bios S.r.l.	infinity medicals	2	https

In vitro diagnostic devices

Update	Access BR Monitor used with the Access Family of Immunoassay Systems	10/31/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	FSN	https ://nc
# New	Alinity hq Analyzers ,	10/30/2017	Abbott	Medical supplies & Services Co.Ltd	2	Attac hed 
New	BC Thrombin Reagent	10/31/2017	Siemens Healthcare Diagnostics I	AL-KAMAL Import	FSN	A/Ca l
# New	Enzygnost HBsAg Assay Kits	10/30/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	2	Attac hed 
New	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor Clone EP1, Ready-to-use	11/2/2017	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	1	https ://nc mdr.
New	NanoZoomer-SQ	10/31/2017	Hamamatsu Corporation	N/A	FSN	A/Ca l
New	STA Neoplastine CI (Plus) 2 and 5	11/2/2017	Diagnostica Stago	Medical supplies & Services Co.Ltd	FSN	https

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Non-active implantable devices

New	Alcon Surgical Procedure Packs	10/30/2017	Alcon Laboratories Inc.	Al Amin Medical Instruments Co. Ltd.	2	https
New	Composite screw LIGAFIX 60 Diam.7 - L:25 mm	10/31/2017	SBM SAS	N/A	FSN	https
New	INTERTAN 10S 10MM X 18CM 130D	10/31/2017	Smith & Nephew inc	Smith & Nephew inc	FSN	https
New	Normed Foot Kelle S. SHOE S. 44 STER	10/31/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https
New	rHead Radial Head and Uni-Elbow System ,	11/1/2017	Stryker Orthopaedics	Zimmo Trading Establishment.	2	https
#	Tactys Distal Stems ,	10/30/2017	Stryker Orthopaedics	nmo Trading Establishme	2	https
#	TunneLoc Tibial Fixation Devices	10/30/2017	Zimmer, INC....	Medical Regulations Gate	2	https











Ophthalmic and optical devices

New	ACUVUE® OASYS® Brand Contact Lenses for ASTIGMATISM with HYDRACLEAR® PLUS	11/2/2017	Johnson & Johnson Vision Care	Allied Medical International	2	https://nc.mdr.
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Reusable devices

New	Heater-Cooler Units HCU 20 and HCU 30.	11/2/2017	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	https
#	Model TJF-Q180V Duodenoscopes	11/5/2017	Olympus	Salehiya Trading Est.	2	https
New	Teleflex(R) Percuvance(TM) Percutaneous Surgical System, Gripper Grasper	11/5/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https://nc.mdr.

Single-use devices

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	Update	Aplicare Povidone Iodine Prep Pads	10/30/2017	Medline Industries Inc...	Ikar Establishment	2	Attac 
#	New	Arrow-Clarke Pleura-Seal Thoracentesis, Large-Volume Abdominal Paracentesis, and Pneumothorax Kits	11/5/2017	Arrow International Inc	Gulf Medical Co.	2	Attac hed 
#	New	Circulatory Technology Better-Bladder Contained in Maquet Custom Tubing Kits ,	10/30/2017	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	2	Attac hed 
	New	Dana Diabecare IIS	10/31/2017	Sooil Development	N/A	FSN	A/Ca
#	New	Disposale Light Handle Covers ,	11/5/2017	Ecolab Inc	Al Hammadmedical Services	2	Attac 
#	New	External Ventricular Drainage Kits ,	10/30/2017	Spiegelberg GmbH & Co KG	Al Amin Medical Instruments Co. Ltd.	2	Attac 
#	New	Gastrostomy and Gastrojejunostomy Sets	10/30/2017	Cook Medical	NAFA Medical	2	Attac 
	New	Hemosphere Monitor, Swan-Ganz Module, Oximetry Cable	11/2/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	FSN	https://nc
#	New	Medline Aplicare Povidone Iodine Prep Pads	11/2/2017	Cardinal Health..	Medical Technology Establishment	2	Attac hed 
#	Update	SENSATION PLUS Intra-Aortic Balloon Catheters with Insertion Kits and STATLOCK	10/30/2017	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	2	Attac hed 
#	New	Surgical Punches ,	11/5/2017	A & E Medical Corp	N/A	2	ttache 
#	New	Various Central Venous Catheter Kits ,	11/5/2017	Arrow International Inc	Gulf Medical Co.	2	Attac 

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Various Teleflex Central Venous Catheter Kits.	11/5/2017	Cardinal Health..	Medical Technology Establishment	2	Attac 
	New	Veletri Consumables Kit with non Flow-Stop CADD Medication Cassette Reservoirs	11/2/2017	Actelion Pharmaceuticals Australia Pty Ltd	N/A	2	https://ncmdr.
	New	Volumed Set (Infusion set)	11/2/2017	Arcomed AG	Al-Faisaliah Medical System	FSN	https

- * 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.